

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

KELLY A. TILLEY, as Personal  
Representative of the Estate of  
DANA ANDREW TILLEY, Deceased,  
  
Plaintiff,  
  
vs.  
  
PFIZER INC., PARKE-DAVIS, a division  
of Warner-Lambert Company and  
Warner-Lambert Company LLC,  
WARNER-LAMBERT COMPANY and  
WARNER-LAMBERT COMPANY LLC,  
  
Defendants.

## **NOTICE OF REMOVAL**

Defendants Pfizer Inc. (“Pfizer”) and Warner-Lambert Company LLC (“Warner-Lambert”), successor to Warner-Lambert Company, on its own behalf and on behalf of its unincorporated division, Parke-Davis (collectively, “Defendants”), by and through their counsel, and, pursuant to 28 U.S.C. §§ 1331, 1441, and 1446 file their Notice of Removal of this matter from the Superior Court of Delaware in and for New Castle County to the United States District Court for the District of Delaware and state as follows:

## I. INTRODUCTION

1. On or about July 7, 2006, plaintiff Kelly A. Tilley filed a wrongful death/products liability action against Defendants in the Superior Court of Delaware in and for New Castle County, styled as *Kelly A. Tilley vs. Pfizer Inc., et al.* Plaintiff alleges that her husband, Dana Tilley, committed suicide as a result of using the prescription drug Neurontin® (“Neurontin”). See Compl. (attached at Exhibit A).

2. Plaintiff served the Complaint on Defendants on July 28, 2006.

3. Under 28 U.S.C. § 1446(b), this removal is timely. This Notice of Removal is being filed within 30 days of service of the Complaint upon Defendants.

## **II. JURISDICTIONAL BASIS FOR REMOVAL**

4. “Federal question” jurisdiction exists if federal law creates the cause of action *or* if a plaintiff’s “right to relief under state law requires resolution of a substantial question of federal law.” *Franchise Tax. Bd. of State of Cal. v. Construction Laborers Vacation Trust*, 463 U.S. 1, 8-9, 13 (1983); *see also Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 125 S. Ct. 2363, 2367 (2005) (“[T]his Court [has] recognized for nearly 100 years that in certain cases federal question jurisdiction will lie over state-law claims that implicate significant federal issues.”).

5. This Court has federal question jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1441 because plaintiff’s claims require resolution of a substantial question of federal law.

### **A. Allegations in the Complaint**

6. In the Complaint, plaintiff brings causes of action for negligence, breach of warranty, strict products liability, and fraud that are inextricably intertwined with, and also arise from, alleged violations of federal law, namely the federal Food, Drug and Cosmetic Act (“FDCA”) and the regulations thereunder.

7. The gravamen of the Complaint is that Defendants engaged in improper off-label promotion and marketing of Neurontin in violation of the FDCA. Indeed, plaintiff establishes what she believes to be the legal support for her allegations in the first ten paragraphs of her “Statement of the Case,” where she sets forth in detail various provisions of the FDCA and its implementing regulations. *See* Compl. ¶¶ 101-110. For example, plaintiff purports to

identify what conduct is prohibited by federal law. “[T]he FDCA prohibits drug manufacturers themselves from marketing and promoting a drug for a use that the FDA has not approved.” *Id.* at ¶ 103 (citing 21 U.S.C. § 331(d)). Plaintiff then states that if a drug manufacturer “desires to market and promote the drug for new uses in addition to those already approved, the materials on ‘off-label’ usage must meet certain stringent requirements [pursuant to federal law] . . . .” *Id.* at ¶ 105.

8. Further, plaintiff explicitly states that the FDCA’s regulations are designed to protect individuals, like plaintiff and plaintiff’s decedent, from the misconduct that she alleges in the Complaint.

The above-described statutory and regulatory system and process is designed to protect the public, including plaintiff, from the dangers arising from drugs which, although approved for a certain specific condition, disease or purpose, could cause injury and harm if used for an ‘off-label’ purpose . . . and to protect the public, including plaintiff’s decedent herein, from the dangers arising from deceptive, misleading, and inaccurate advertising, marketing, and promotional materials issued directly or indirectly by the manufacturer to encourage the ‘off-label’ usage of the drug . . . .

*Id.* at ¶ 106.

9. After establishing the rigors of the FDCA, plaintiff alleges that Defendants repeatedly violated various of its provisions.

10. Plaintiff alleges that Parke-Davis obtained permission from the Food and Drug Administration (“FDA”) in 1993 to market and promote the prescription drug Neurontin under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* See Compl. ¶ 107. Plaintiff further alleges that the FDA approved the drug for use as adjunctive therapy, *i.e.*, as a drug to be used in conjunction with other drugs to treat certain types of seizures in adult patients with epilepsy at maximum dosages of 1800 milligrams per day, and that Defendants did not receive

FDA approval for any other use of Neurontin prior to plaintiff's decedent's being prescribed the drug. *Id.* at ¶¶ 107-08.

11. Further, plaintiff asserts that despite the lack of FDA approval, in 1995, Defendants allegedly began to directly and indirectly advertise, market and promote Neurontin for off-label uses, and repeatedly decided not to seek FDA approval for certain off-label uses. *Id.* at ¶¶ 109-117; 153-219. Specifically, plaintiff alleges that Defendants "determined not to seek FDA approval for certain unapproved uses." *Id.* at ¶ 159.

12. In Paragraphs 165 through 219 of the Complaint, plaintiff sets forth numerous allegations regarding Defendants' alleged advertising, marketing, and promotion of Neurontin for off-label uses.

13. For example, plaintiff alleges that "[t]he FDA determined [Parke Davis's] application [for a supplemental NDA as a treatment for seizures] to be non-approvable . . . because of insufficiency of evidence of Neurontin's effectiveness" but that Defendants continued to promote Neurontin for the treatment of seizures. *Id.* at ¶ 190. In addition, plaintiff alleges that "[n]otwithstanding the FDA's refusal to increase the maximum approved dosage of Neurontin . . . defendants presented numerous programs where physician participants asserted that Neurontin was effective and safe at dosages above 1800 mg." *Id.* at ¶ 192.

14. Plaintiff further asserts that Defendants' promotion and advertising of Neurontin was improper because it violated *federal law* in numerous ways, including but not limited to, "illegally promoting the sale and use of Neurontin for [off-label uses] . . . in violation of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 331, et seq.; [and,] offering and paying illegal remuneration to doctors . . . to induce them to promote and prescribe Neurontin for

off-label uses, in violation of the federal Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b).” *Id.* at ¶ 195.

15. In sum, Paragraph 116 of the Complaint succinctly summarizes the gist of the allegations in the Complaint and illustrates how plaintiff’s claims are inextricably intertwined with federal law:

Neurontin is not reasonably safe and effective for the treatment of persons suffering from pain and migraines, and is not reasonably safe when consumed in higher doses than those approved by the FDA, and the defendants’ conduct of illegally advertising, marketing and promoting Neurontin for this ‘off-label’ use was unlawful, deceptive and misleading and was violative of the FDCA.

*Id.* at ¶ 116. Resolution of plaintiff’s claims, therefore, will require the court to interpret the various provisions of the FDCA and resolve a substantial question of federal law.

#### **B. Jurisdiction**

16. This Court has removal jurisdiction because this is a civil action “of which the district courts have original jurisdiction” and an action “founded on a claim or right arising under the . . . laws of the United States.” 28 U.S.C. § 1441(a), (b); *see* 28 U.S.C. § 1331.

17. Federal question jurisdiction exists in this action because plaintiff’s claims are not only inextricably intertwined with, but also arise from, alleged violations of federal statutes and regulations. The gravamen of plaintiff’s claims is that Defendants’ alleged off-label “marketing program” violated federal law in numerous ways. A substantial federal question unmistakably resides at the heart of this action.

18. The resolution of plaintiff’s allegations necessarily turns on the construction of federal law, namely whether Defendants violated the FDCA or FDA regulations. *See City of Chicago v. Int’l Coll. of Surgeons*, 522 U.S. 156, 164 (1997) (“[E]ven though state law creates [a party’s] causes of action, its case might still ‘arise under’ the laws of the United

States if a well-pleaded complaint established that its right to relief under state law requires resolution of a substantial question of federal law.”) (internal quotation marks omitted). Indeed, it will not be possible to determine whether plaintiff may prevail on her state-law claims without first resolving these intricate issues of federal law.

19. Because plaintiff’s claims rely upon the interpretation and application of the FDCA and FDA regulations, and given that a plaintiff may not defeat removal by failing to plead necessary federal questions, a federal court is the proper forum for addressing these claims. Nowhere in the Complaint does plaintiff disclaim her intent to rely on a violation of federal law to establish liability under her state-law claims. Absent any disavowal of such reliance, and in light of plaintiff’s express reliance on federal law, it is evident that interpretation of federal law is essential to the adjudication of plaintiff’s claims.

20. Allowing individual state courts to make determinations regarding a pharmaceutical manufacturer’s marketing of prescription drugs, which is heavily regulated by the FDA, would disrupt the federal regulatory scheme. The need for uniform interpretation and enforcement of the FDCA and FDA regulations underscores the appropriateness of removal of this action.

21. Moreover, lawsuits alleging similar unfair business practices as this case and brought on behalf of purchasers of Neurontin, including nationwide classes that purport to include plaintiff, have been filed in a number of United States District Courts, including those in the Southern District of New York, Eastern District of Arkansas, Southern District of Alabama, Northern District of Florida, Northern District of Georgia, Southern District of Illinois, Western District of Missouri, District of Nebraska, and numerous others already assigned, and others in the process of being assigned, to a multidistrict proceeding in the District of Massachusetts

styled, *In re Neurontin Marketing, Sales Practices and Products Liability Litigation*, MDL-1629. Because a case is properly removable if it could have been filed in the first instance in federal court, it is significant that lawsuits grounded upon the same set of facts as those alleged here have, in fact, already been filed in federal courts across the country.

22. The thorny issue of whether federal question jurisdiction exists over a Neurontin plaintiff's claims purportedly brought under state law has arisen in other Neurontin cases and is likely to arise in future cases. Indeed, a number of cases already transferred to the Neurontin MDL (or pending transfer) raise this same jurisdictional question. *See, e.g., Eckenrode v. Pfizer Inc.*, No. 3:04-cv-240/MCR/MD (N.D. Fla.); *Johnson v. Pfizer Inc.*, No. 05-3688 (E.D. La.); *Craft v. Pfizer Inc.*, No. 2:05-cv-310-FtM-33SPC (M.D. Fla.); *Blackwell v. Pfizer Inc.*, No. 06-2295 (E.D. Pa.). As such, the MDL Court is the proper forum to decide this issue to promote "judicial economy and consistency," which is the purpose of the MDL proceeding. *In re Ivy*, 901 F.2d 7, 9 (2d Cir. 1990) (upholding MDL Panel's rejection of plaintiffs' request that remand motion be decided by transferor court; holding that "[t]he jurisdictional issue in question is easily capable of arising in hundreds or even thousands of cases in district courts throughout the nation," and that "[c]onsistency as well as economy is . . . served" if "the jurisdictional objections [are] heard and resolved by a single court").

23. Other district courts in the Third Circuit are in accord with this view. In another Neurontin-related action, *Blackwell v. Pfizer Inc.*, filed this May in the Court of Common Pleas, Philadelphia County, Pennsylvania, Defendants removed the action to the Eastern District of Pennsylvania on federal questions grounds. Plaintiffs filed a motion to remand the case. The Honorable Bruce W. Kauffman granted Defendants' Motion to Stay Proceedings Pending MDL Transfer without ruling on the remand motion, thereby allowing the

MDL Court to decide the jurisdictional issue in a uniform manner. *See Blackwell v. Pfizer Inc.*, No. 06-2295, slip op. at 1 (E.D. Pa. July 19, 2006) (granting motion to stay pending MDL transfer) (attached as Exhibit B). *See also Young v. Pfizer Inc.*, No. 06-1308, slip op. at 1 (E.D. Pa. May 4, 2006) (granting a motion to stay in another Neurontin case pending MDL transfer despite a pending remand motion) (attached as Exhibit C).

24. The MDL Court is best positioned to decide this jurisdictional issue because it (i) has already arisen in Neurontin cases and is likely to arise in future Neurontin actions and (ii) presents a matter of first impression in several circuits, including the Third Circuit, in light of the Supreme Court's decision in *Grable*. In *Grable*, the Court corrected interpretations of *Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804 (1986), that required a federal cause of action as a condition for finding federal question jurisdiction. *See* 125 S. Ct. at 2371 n.7. *Grable* held that there is not one "single, precise, all-embracing" test for jurisdiction over federal issues embedded in state-law claims" and that determining whether federal question jurisdiction exists requires "a contextual enquiry." *Id.* at 2368, 2370.

25. Since *Grable*, two federal district courts in the Second Circuit have been asked to decide whether federal question jurisdiction existed over products liability claims purportedly brought under state law, but based on allegations that the defendant violated provisions of the FDCA. The two courts reached inconsistent results. *Compare In re Zyprexa Prods. Liab. Litig.*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005) (holding that federal question jurisdiction existed over state-law claims because "the substantial federal funding provisions involved and the allegations about the violation of federal law through *improper off-label use* present a core of substantial issues" and, therefore, "[f]ederal jurisdiction lies under *Grable*." (emphasis added), with *Caggiano v. Pfizer Inc.*, 384 F. Supp. 2d 689 (S.D.N.Y. 2005) (holding

that it lacked federal question jurisdiction over state-law claims of improper marketing and promotion of Neurontin).<sup>1</sup>

26. Defendants respectfully submit that the MDL Court is best suited to decide this complex issue in the Neurontin litigation. *See Moore v. Wyeth-Ayerst Labs.*, 236 F. Supp. 2d 509, 512 (D. Md. 2002) (granting motion to stay pending MDL transfer; “[t]he transferee court has . . . intimate familiarity with the issues involving products liability claims arising from the use of [the subject product]”); *Johnson v. AMR Corp.*, Nos. 95-C-7659 – 95-C-7664, 1996 WL 164415, at \*4 (N.D. Ill. Apr. 3, 1996) (noting that the MDL has the advantage of “looking at the forest as well as the trees” and finding that upon transfer “it is far better for [the MDL judge] to resolve the jurisdictional question”).

### **III. OTHER PROCEDURAL MATTERS**

27. Pursuant to 28 U.S.C. §§ 1441(a) and 1446(a), the United States District Court for the District of Delaware is the appropriate court for filing a Notice of Removal from the Superior Court of Delaware in and for New Castle County. *See* 28 U.S.C. § 87.

28. Pursuant to 28 U.S.C. § 1446(a), Defendants have attached hereto copies of all process, pleadings and orders served upon Defendants. *See* Exhibit A.

29. Pursuant to 28 U.S.C. § 1446(d), Defendants shall give plaintiff written notice of the filing of this Notice of Removal and Defendants shall file the written notice of having filed this Notice of Removal with the clerk of the Superior Court of Delaware in and for New Castle County, attaching thereto a copy of this Notice of Removal.

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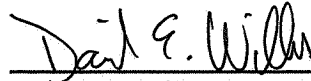
<sup>1</sup> In addition to *Caggiano*, another district court determined that federal question jurisdiction did not exist over a Neurontin case involving similar allegations to this case. *See Rubel v. Pfizer Inc.*, 276 F. Supp. 2d 904 (N.D. Ill. 2003), *appeal dismissed*, 361 F.3d 1016 (7th Cir. 2004). The *Rubel* decision, however, pre-dated *Grable* and involved a local rule in the Northern District of Illinois that is not at issue here.

WHEREFORE, Defendants give notice that the matter styled as *Kelly A. Tilley vs. Pfizer Inc., et al.*, Civil Action No. 06C-07-046 RRC, which was filed on or about July 7, 2006, in the Superior Court of Delaware in and for New Castle County is removed to the United States District Court for the District of Delaware.

Dated: August 17, 2006

Respectfully submitted,

REED SMITH LLP

By:   
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*Attorneys for Defendants*

# **EXHIBIT A**

EFiled: Jul 7 2006 2:01PM  
Transaction ID 11728078



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE  
IN AND FOR NEW CASTLE COUNTY

KELLY A. TILLEY, as Personal  
Representative of the Estate of  
DANA ANDREW TILLEY, Deceased,

Plaintiff,

v.

PFIZER INC., PARKE-DAVIS,  
a division of Warner-Lambert Company  
and Warner-Lambert Company LLC,  
WARNER-LAMBERT COMPANY and  
WARNER-LAMBERT COMPANY LLC,

Defendants,

C.A. No. 06C-07-046 RRC

SUMMONS

THE STATE OF DELAWARE  
TO THE SHERIFF OF NEW CASTLE COUNTY:  
YOU ARE COMMANDED:

To summon the above named defendant so that, within 20 days after service hereof upon defendant, exclusive of service, defendant shall serve upon Ramunno, Ramunno & Scerba, P.A., Plaintiff's attorney, whose address is 903 French Street, Wilmington, DE 19801, an answer to the Complaint (and, if the complaint contains a specific notation requiring the defendant to answer any or all allegations of the complaint by affidavit, an affidavit of defense).

To serve upon defendant a copy hereof and of the complaint.

Dated:

7/26/06

SHARON AGNEW  
Prothonotary  
Per Deputy

TO THE ABOVE NAMED DEFENDANT:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiff's attorney named above an answer to the complaint (and, if the complaint contains a specific notation requiring the defendant to answer any or all allegations of the complaint by affidavit or defense), judgment by default will be rendered against you for the relief demanded in the complaint.

SHARON AGNEW  
Prothonotary  
Per Deputy

SUPERIOR COURT CIVIL CASE INFORMATION STATEMENT (CIS) 006 2:01P  
Transaction ID 11728078COUNTY: N K S  
Civil Case Code CPINCIVIL ACTION NUMBER: 06C-07-046 RRCCivil Case Type Personal Injury

(SEE REVERSE SIDE FOR CODE AND TYPE)



<p>Caption:  <b>KELLY A. TILLEY, as Personal Representative of the Estate of DANA ANDREW TILLEY, Deceased,</b>          Plaintiff,</p> <p>VS.</p> <p><b>PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC,</b>          Defendants.</p>	<p>Name and Status of Party filing document:  <b>KELLY A. TILLEY, as Personal Representative of the Estate of DANA ANDREW TILLEY, Deceased</b></p> <p>Document Type: (E.G., COMPLAINT; ANSWER WITH COUNTERCLAIM)  <b>COMPLAINT</b></p> <p>Non-Arbitration <input checked="" type="checkbox"/> (CERTIFICATE OF VALUE MAY BE REQUIRED)</p> <p>Arbitration <input type="checkbox"/> Mediation <input type="checkbox"/> Neutral Assessment <input type="checkbox"/></p> <p>DEFENDANT (CIRCLE ONE) <b>ACCEPT REJECT</b></p> <p>JURY DEMAND YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p> <p>TRACK ASSIGNMENT REQUESTED (CIRCLE ONE)  <b>EXPEDITED<sup>x</sup> STANDARD COMPLEX</b></p>
<p>ATTORNEY NAME(S):  <b>Lawrence A. Ramunno, Esq.</b></p> <p>ATTORNEY ID(S):  <b>Ramunno, Ramunno &amp; Scerba, P.A.</b></p> <p>FIRM NAME:  <b>903 French Street</b></p> <p>ADDRESS:  <b>Wilmington, DE 19801</b></p> <p>TELEPHONE NUMBER:  <b>302-656-9400</b></p> <p>FAX NUMBER:  <b>302-656-9344</b></p> <p>E-MAIL ADDRESS:  <b>rrsattorneys@aol.com</b></p>	<p>IDENTIFY ANY RELATED CASES NOW PENDING IN THE SUPERIOR COURT BY CAPTION AND CIVIL ACTION NUMBER INCLUDING JUDGE'S INITIALS  <b>n/a</b></p> <p>EXPLAIN THE RELATIONSHIP(S):  <b>n/a</b></p> <p>OTHER UNUSUAL ISSUES THAT AFFECT CASE MANAGEMENT:</p> <p>(IF ADDITIONAL SPACE IS NEEDED, PLEASE ATTACH PAGE)</p>

THE PROTHONOTARY WILL NOT PROCESS THE COMPLAINT, ANSWER, OR FIRST RESPONSIVE PLEADING IN THIS MATTER FOR SERVICE UNTIL THE CASE INFORMATION STATEMENT (CIS) IS FILED. THE FAILURE TO FILE THE CIS AND HAVE THE PLEADING PROCESSED FOR SERVICE MAY RESULT IN THE DISMISSAL OF THE COMPLAINT OR MAY RESULT IN THE ANSWER OR FIRST RESPONSIVE PLEADING BEING STRICKEN.

Revised 6/2002

EFiled: Jul 7 2006 2:01PM  
Transaction ID 11728078



**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE  
IN AND FOR NEW CASTLE COUNTY**

KELLY A. TILLEY, as Personal  
Representative of the Estate of  
DANA ANDREW TILLEY, Deceased,

Plaintiff,

vs.

PFIZER INC., PARKE-DAVIS,  
a division of Warner-Lambert Company  
and Warner-Lambert Company LLC,  
WARNER-LAMBERT COMPANY and  
WARNER-LAMBERT COMPANY LLC,

Defendants.

Civil Action No. 06C-07-046 RRC

**NON-ARBITRATION CASE**

**JURY OF TWELVE DEMANDED**

**COMPLAINT**

Plaintiff, KELLY A. TILLEY (alternatively referred to as "Plaintiff"), by and through her undersigned attorneys, and for her Complaint against Defendants, PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC (hereinafter referred to as "PARKE-DAVIS"), WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC (hereinafter collectively referred to as "Defendants"), aver on knowledge as to herself and her own acts and on information and belief as to all other matters, as follows:

**NATURE OF THE ACTION**

1. Plaintiff, KELLY A. TILLEY, as Personal Representative of the Estate of plaintiff's decedent, DANA ANDREW TILLEY, brings this action on behalf of herself and for the benefit of all statutory beneficiaries under the laws of the State of Delaware, 10

Del. C. §§ 3701 and 3724, to recover damages for personal injuries sustained by, and the wrongful death of, plaintiff's decedent, as the direct and proximate result of Defendants' wrongful conduct in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the prescription drug Neurontin, especially for such "off-label" uses as the treatment of pain, even though Neurontin had not received FDA approval for such use, and at dosages higher than had been approved by the FDA and had been properly tested on humans, even though the drug had not been tested and studied for such use and had not been found to be safe and effective at any dosage for the treatment of pain and migraines.

#### **PARTIES**

2. That the above-named plaintiff's decedent, DANA ANDREW TILLEY, was the Husband and Next of Kin of the Personal Representative above-named, KELLY A. TILLEY, and on and prior to the 9<sup>th</sup> day of July, 2002, the Deceased and Personal Representative resided at 103 Pigeon Run Drive, Bear, New Castle County, Delaware 19701.

3. That prior to the commencement of this action, Letters of Administration were granted by the Register of Wills for New Castle County, State of Delaware, to the plaintiff, KELLY A. TILLEY, appointing her as Personal Representative of the Estate of the deceased, DANA ANDREW TILLEY, on the 5<sup>th</sup> day of July, 2006, and at all times hereinafter mentioned, duly qualified and entered upon her duties as such Personal Representative and is now acting in such capacity. A copy of said Letters are attached hereto.

4. That at the time of plaintiff's decedent's death on July 9, 2002, he was survived by his wife, the plaintiff, KELLY A. TILLEY, who resides at 103 Pigeon Run Drive, Bear, Delaware 19701, his son, Joshua I. Tilley, who resides at 103 Pigeon Run Drive, Bear, Delaware 19701, his son, Robert A. Tilley, who resides at 103 Pigeon Run Drive, Bear, Delaware 19701, and his daughter, Chasitie L. Tilley, who resides at Beaufort, South Carolina.

5. That at the time of death on July 9, 2002, plaintiff's decedent was then the age of 37 years and prior thereto, was generally in good health, industrious and possessed all faculties.

6. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., was and still is a domestic corporation organized under the laws of the State of Delaware.

7. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., was and still is a domestic corporation authorized to do business in the State of Delaware.

8. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., was and still is a business entity actually doing business in the State of Delaware.

9. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC (hereinafter "PARKE-DAVIS"), was and still is a foreign corporation organized under the laws of the State of Michigan.

10. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, was and still is a foreign corporation authorized to do business in the State of Delaware.

11. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, was and still is a business entity actually doing business in the State of Delaware.

12. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY was a domestic corporation organized under the laws of the State of Delaware.

13. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, was a domestic corporation authorized to do business in the State of Delaware.

14. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, was and still is a business entity actually doing business in the State of Delaware.

15. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a division of the defendant, WARNER-LAMBERT COMPANY.

16. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a subsidiary of the defendant, WARNER-LAMBERT COMPANY.

17. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was and still is a domestic limited liability company organized under the laws of the State of Delaware.

18. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was and still is a domestic limited liability company authorized to do business in the State of Delaware.

19. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was and still is a business entity actually doing business in the State of Delaware.

20. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is the sole shareholder and member of the defendant, WARNER-LAMBERT COMPANY LLC.

21. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a division of the defendant, WARNER-LAMBERT COMPANY LLC.

22. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a subsidiary of the defendant, WARNER-LAMBERT COMPANY LLC.

23. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a division of the defendant, PFIZER INC.

24. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a subsidiary of the defendant, PFIZER INC.

25. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a successor in interest to the defendant, PARKE-DAVIS.

26. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a division of the defendant, PFIZER INC.

27. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a subsidiary of the defendant, PFIZER INC.

28. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a successor in interest to the defendant, PARKE-DAVIS.

29. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a successor in interest to the defendant, PARKE-DAVIS.

30. That on a date prior to July 9, 2002, the defendant, WARNER-LAMBERT COMPANY, assumed the assets and liabilities of the defendant, PARKE-DAVIS.

31. That on a date prior to July 9, 2002, the defendant, WARNER-LAMBERT COMPANY, expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

32. That on a date prior to July 9, 2002, the defendant, WARNER-LAMBERT COMPANY, impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

33. That on a date prior to July 9, 2002, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY, merged with each other.

34. That on a date prior to July 9, 2002, the defendant, PARKE-DAVIS, merged with the defendant, WARNER-LAMBERT COMPANY, and the defendant, PARKE-DAVIS, became a part of the defendant, WARNER-LAMBERT COMPANY.

35. That on a date prior to July 9, 2002, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY, consolidated with each other.

36. That on or about December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, assumed the assets and liabilities of the defendant, PARKE-DAVIS.

37. That on or about December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

38. That on or about December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

39. That on or about December 31, 2002, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

40. That on or about December 31, 2002, the defendant, PARKE-DAVIS, merged with the defendant, WARNER-LAMBERT COMPANY LLC, and the defendant, PARKE-DAVIS, became a part of the defendant, WARNER-LAMBERT COMPANY LLC.

41. That on or prior to December 31, 2002, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY LLC, consolidated with each other.

42. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a successor in interest to the defendant, WARNER-LAMBERT COMPANY.

43. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY.

44. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

45. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, impliedly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

46. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY, and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

47. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY, merged with the defendant, WARNER-LAMBERT COMPANY

LLC, and the defendant, WARNER-LAMBERT COMPANY, became a part of the defendant, WARNER-LAMBERT COMPANY LLC.

48. That on or prior to December 31, 2002, the defendant, WARNER-LAMBERT COMPANY, and the defendant, WARNER-LAMBERT COMPANY LLC, consolidated with each other.

49. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is a successor in interest to the defendant, PARKE-DAVIS.

50. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is a successor in interest to the defendant, WARNER-LAMBERT COMPANY.

51. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is a successor in interest to the defendant, WARNER-LAMBERT COMPANY LLC.

52. That on a date prior to July 9, 2002, the defendant, PFIZER INC., assumed the assets and liabilities of the defendant, PARKE-DAVIS.

53. That on a date prior to July 9, 2002, the defendant, PFIZER INC., assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY.

54. That on a date prior to July 9, 2002, the defendant, PFIZER INC., expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

55. That on a date prior to July 9, 2002, the defendant, PFIZER INC., impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

56. That on a date prior to July 9, 2002, the defendant, PFIZER INC., expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

57. That on a date prior to July 9, 2002, the defendant, PFIZER INC., impliedly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

58. That on or prior to December 31, 2002, the defendant, PFIZER INC., assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY LLC.

59. That on or prior to December 31, 2002, the defendant, PFIZER INC., expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY LLC.

60. That on or prior to December 31, 2002, the defendant, PFIZER INC., impliedly assumed all liabilities and obligations of the defendant WARNER-LAMBERT COMPANY LLC.

61. That on a date prior to July 9, 2002, the defendant, PFIZER INC., and the defendant, PARKE-DAVIS, merged with each other.

62. That on a date prior to July 9, 2002, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY, merged with each other.

63. That on or before July 9, 2002, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

64. That on a date prior to July 9, 2002, the defendant, PFIZER INC., and the defendant, PARKE-DAVIS, merged with each other and the defendant, PARKE-DAVIS, became a part of the defendant, PFIZER INC.

65. That on a date prior to July 9, 2002, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY, merged with each other and the defendant, WARNER-LAMBERT COMPANY, became a part of the defendant, PFIZER INC.

66. That on or prior to December 31, 2002, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other and the defendant, WARNER-LAMBERT COMPANY LLC, became a part of the defendant, PFIZER INC.

67. That on a date prior to July 9, 2002, the defendant, PFIZER INC., and the defendant, PARKE-DAVIS, consolidated with each other.

68. That on a date prior to July 9, 2002, the defendant, PFIZER INC., and the defendant, WARNER-LAMBERT COMPANY, consolidated with each other.

69. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., has its principal place of business in the State of New York.

70. In the year 2000, the defendant, PFIZER INC., acquired the defendant, WARNER-LAMBERT COMPANY, and as the result of that acquisition, the defendant, PFIZER INC., is responsible for all liabilities resulting from the acts or omissions of the defendant, WARNER-LAMBERT COMPANY, which occurred prior to such acquisition.

71. In the year 2000, the defendant, PFIZER INC., acquired the defendant, PARKE-DAVIS, a division of Warner-Lambert Company, and as the result of that

acquisition, the defendant, PFIZER INC., is responsible for all liabilities resulting from the acts or omissions of the defendant, PARKE-DAVIS, which occurred prior to such acquisition.

72. On or prior to December 31, 2002, defendant, PFIZER INC., acquired the defendant, WARNER-LAMBERT COMPANY LLC, and pursuant to the terms of and conditions of that acquisition, the defendant, PFIZER INC., is responsible for all acts or omissions of the defendant, WARNER LAMBERT-COMPANY, LLC, occurring prior to such acquisition.

73. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., presently markets and sells the drug Neurontin.

74. That on a date prior to July 9, 2002, the defendant, PFIZER INC., marketed and sold the drug Neurontin.

75. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of Delaware and contracts to provide goods and services in the State of Delaware.

76. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., committed a tortious act inside the State of Delaware, which caused injury to plaintiff's decedent inside the State of Delaware.

77. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., committed a tortious act outside the State of Delaware, which caused injury to plaintiff's decedent inside the State of Delaware.

78. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., regularly does and solicits business and engages in a persistent course of conduct in the State of Delaware, deriving substantial revenue from goods and products consumed in the State of Delaware.

79. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER INC., expects or should reasonably expect its acts to have consequences in the State of Delaware, and derives substantial revenue from interstate or international commerce.

80. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, presently markets and sells the drug Neurontin.

81. That on a date prior to July 9, 2002, the defendant, PARKE-DAVIS, marketed and sold the drug Neurontin.

82. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of Delaware and contracts to provide goods and services in the State of Delaware.

83. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, committed a tortious act inside the State of Delaware, which caused injury to plaintiff's decedent inside the State of Delaware.

84. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, committed a tortious act outside the State of Delaware, which caused injury to plaintiff's decedent inside the State of Delaware.

85. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, regularly does and solicits business and engages in a persistent course of conduct in the State of Delaware, deriving substantial revenue from goods and products consumed in the State of Delaware.

86. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, expects or should reasonably expect its acts to have consequences in the State of Delaware, and derives substantial revenue from interstate or international commerce.

87. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, presently markets and sells the drug Neurontin.

88. That on a date prior to July 9, 2002, the defendant, WARNER-LAMBERT COMPANY, marketed and sold the drug Neurontin.

89. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of Delaware and contracts to provide goods and services in the State of Delaware.

90. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, committed a tortious act inside the State of Delaware, which caused injury to plaintiff's decedent in the State of Delaware.

91. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, committed a tortious act outside the State of Delaware, which caused injury to plaintiff's decedent inside the State of Delaware.

92. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, regularly does and solicits business and engages in a persistent course of conduct in the State of Delaware, deriving substantial revenue from goods and products consumed in State of Delaware.

93. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, expects or should reasonably expect its acts to have consequences in the State of Delaware, and derives substantial revenue from interstate or international commerce.

94. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, presently markets and sells the drug Neurontin.

95. That on a date prior to July 9, 2002, the defendant, WARNER-LAMBERT COMPANY LLC, marketed and sold the drug Neurontin.

96. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of Delaware.

97. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, committed a tortious act inside the

State of Delaware, which caused injury to plaintiff's decedent inside the State of Delaware.

98. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, committed a tortious act outside the State of Delaware, which caused injury to plaintiff's decedent inside the State of Delaware.

99. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, regularly does and solicits business and engages in a persistent course of conduct in the State of Delaware, deriving substantial revenue from good and products consumed in the State of Delaware.

100. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, regularly does and solicits business and engages in a persistent course of conduct in the State of Delaware, deriving substantial revenue from interstate commerce.

## **BACKGROUND**

### **STATEMENT OF THE CASE**

101. Pursuant to the Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. §§ 301 et seq., new pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a) and (d).

102. However, the FDCA does not prevent doctors from prescribing a drug approved for a particular use for other uses that are different than those approved by the FDA ("off-label" usage).

103. Nonetheless, even though physicians may prescribe drugs for "off-label" usage, the FDCA prohibits drug manufacturers themselves from marketing and promoting a drug for a use that the FDA has not approved. 21 U.S.C. § 331(d).

104. A manufacturer illegally "misbrands" a drug if the drug's labeling includes information about unapproved uses or if the manufacturer engages directly or indirectly in marketing or promoting the drug for unapproved uses.

105. Instead, if a manufacturer desires to market and promote the drug for new uses in addition to those already approved, the materials on "off-label" usage must meet certain stringent requirements and the manufacturer must resubmit the drug to the FDA testing and approval process for the proposed new use.

106. The above-described statutory and regulatory system and process is designed to protect the public, including plaintiff, from the dangers arising from drugs which, although approved for a certain specific condition, disease or purpose, could cause injury and harm if used for an "off-label" purpose without adequate study and testing of the drug for such "off-label" usage, and to protect the public, including plaintiff's decedent herein, from the dangers arising from deceptive, misleading, and inaccurate advertising, marketing, and promotional materials issued directly or indirectly by the manufacturer to encourage the "off-label" usage of the drug without adequate testing and study of that drug for such "off-label" usage.

107. PARKE-DAVIS, now owned by PFIZER INC., applied for, and in December, 1993, received FDA approval to market and sell Neurontin solely for "adjunctive therapy" in the treatment of certain types of seizures in adult patients suffering from epilepsy, and the FDA approved labeling of Neurontin for that purpose and stated that the drug is only effective at 900 to 1800 milligrams per day.

108. At no time prior to plaintiff's decedent being prescribed Neurontin, did defendants receive FDA approval for any other use of Neurontin except for the above-described treatment of epilepsy or for higher dosages for any purpose, and the FDA never approved the usage of Neurontin at any dosage for the treatment of pain and migraines.

109. Commencing in 1995, defendants, as the manufacturer of Neurontin, began to directly and indirectly advertise, market and promote Neurontin for additional "off-label" uses for which FDA approval had not been obtained, including treatment for pain and migraines and at higher dosages than had been tested and approved, in violation of the above-described statutory and regulatory system and process, including the FDCA, which prohibits manufacturers from directly or indirectly advertising, marketing and promoting a drug for "off-label" usage, and instead requires that the manufacturer resubmit the drug to the FDA testing and approval process for the proposed new use and that the materials issued by the manufacturer relating to the proposed new use meet certain stringent requirements.

110. Defendants, as the manufacturers of Neurontin, directly and indirectly advertised, marketed and promoted Neurontin for the treatment of pain and migraines and encouraged that higher dosages than those tested be prescribed, even though

defendants knew or should have known that there were not adequate tests and studies establishing and confirming that Neurontin was safe and effective for the treatment of pain and migraines, and even though defendants knew or should have known that there were no adequate studies showing that Neurontin was safe when prescribed at dosages higher than those approved by the FDA.

111. At all times hereinafter mentioned, upon information and belief, defendants marketed and promoted Neurontin for the treatment of pain and migraines even though defendants knew or should have known that Neurontin caused many symptoms or related risk factors associated with suicidal behavior by persons suffering from pain and migraines.

112. At all times hereinafter mentioned, upon information and belief, defendants marketed and promoted Neurontin for the treatment of pain and migraines even though defendants knew or should have known that Neurontin had no effect in relieving or correcting the symptoms or causes of pain and migraines.

113. Defendants' conduct in promoting "off-label" uses of Neurontin for treatment of pain and migraines constituted a wanton, callous and reckless disregard of the safety of the public and, in particular of persons suffering from pain and migraines.

114. In promoting "off-label" uses of Neurontin, and at higher dosages than approved by the FDA, including treatment of pain and migraines, defendants acted without regard to the potential danger and harm to persons for whom the drug was prescribed for the treatment of pain and migraines.

115. Defendants actively distributed, sold and placed Neurontin into the stream of commerce and directly and indirectly advertised, marketed and promoted Neurontin

as being safe and effective for the treatment of pain and migraines and in dosages higher than those approved by the FDA, even though the only approved use of Neurontin at that time was as "adjunctive therapy" for the treatment of epilepsy and even though the FDA had specified a maximum recommended dosage.

116. Neurontin is not reasonably safe and effective for the treatment of persons suffering from pain and migraines, and is not reasonably safe when consumed in higher dosages than those approved by the FDA, and defendants' conduct of illegally advertising, marketing and promoting Neurontin for this "off-label" uses was unlawful, deceptive and misleading and was violative of the FDCA.

117. By reason of defendants' conduct of directly and indirectly advertising, marketing and promoting Neurontin for the treatment of pain and migraines in an unlawful manner, physicians commenced prescribing Neurontin to their patients diagnosed as suffering from pain and migraines, frequently at dosages higher than those approved by the FDA.

118. Upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was indicted in the United States District Court for the District of Massachusetts for violations of 21 U.S.C. §§ 331(a), 331(d), 333(a), 352(f)(1) and 355, and a copy of such criminal Information is annexed hereto as Exhibit "A" and incorporated into this complaint by reference.

119. Upon information and belief, on or about the 7<sup>th</sup> day of June, 2004, the defendant, WARNER-LAMBERT COMPANY LLC, formally pled guilty to all charges contained in the Information.

120. The drug Neurontin was ineffective in the treatment of the causes and symptoms of plaintiff's decedent's condition of pain and migraines and plaintiff's decedent sustained injury and harm by reason of this reliance upon Neurontin to be effective in the treatment as prescribed by his physician of such pain and migraines condition.

121. That at all times hereinafter mentioned, plaintiff's decedent was diagnosed by his physician as suffering from pain and migraines and was being treated by his physician for such condition.

122. That at all times hereinafter mentioned, upon information and belief, in reliance upon defendants' direct and indirect advertising, marketing and promoting of Neurontin as being safe and effective for the treatment of pain and migraines, plaintiff's decedent's physician prescribed Neurontin to treat plaintiff's decedent's pain and migraines.

123. That at all times hereinafter mentioned, plaintiff's decedent purchased and consumed Neurontin, as recommended and prescribed by his physician and in the dosages prescribed, in an effort to control the effects of pain and migraines.

124. The drug Neurontin was not safe and effective for the treatment of plaintiff's decedent's condition of pain and migraines, and plaintiff's decedent sustained injury and harm by reason of his consumption of Neurontin as prescribed by his physician in an effort to treat his pain and migraines.

125. The drug Neurontin was ineffective in the treatment of the causes and symptoms of plaintiff's decedent's condition of bipolar disorder and plaintiff's decedent

sustained injury and harm by reason of this reliance upon Neurontin to be effective in the treatment as prescribed by his physician of such pain and migraines.

126. By reason of plaintiff's decedent's consumption of Neurontin in a manner and at a dosage prescribed by his physician in an effort to treat his pain and migraines, on July 9, 2002, plaintiff's decedent committed suicide.

127. The injuries and death sustained by plaintiff's decedent were caused by or were contributed to by plaintiff's decedent's consumption of Neurontin at a dosage prescribed by his physician for the treatment of pain and migraines in a manner consistent with the direct and indirect advertising, marketing and promoting of this drug for such "off-label" use by defendants.

#### **COUNT I**

#### **NEGLIGENCE**

128. Plaintiff repeats and reiterates the allegations previously set forth herein.

129. That at all times hereinafter mentioned, defendants were under a duty to exercise reasonable care in the design and development of Neurontin and, in particular, in the advertising, marketing and promoting of Neurontin, both directly and indirectly, to ensure that Neurontin was not used in the treatment of conditions such as pain and migraines for which it was not effective and to ensure that Neurontin was not used in a manner or to treat conditions where defendants knew or should have known that the user could sustain injuries and harm from the drug.

130. That defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by

the manner that defendants, directly and indirectly, advertised, marketed and promoted Neurontin for the treatment of pain and migraines, even though Neurontin had not been scientifically determined to be safe for the treatment of such condition and even though Neurontin was, in fact, not reasonably safe for the treatment of such condition and furthermore, defendant failed to adequately warn of the risk of suicide or aggressive, self-destructive behavior of which defendants knew or should have known about.

131. That defendants were further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Neurontin even though such drug was not safe or effective for any purpose because it caused or influenced persons using the drug for any purpose to engage in self-destructive behavior including committing suicide and by failing to adequately warn the public of such risks.

132. The death of plaintiff's decedent was caused by or was contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including plaintiff's decedent, on the part of defendants in the design, manufacture, distribution, advertising, marketing and promoting of Neurontin as being safe and effective treatment of pain and migraines and by inducing the public, including plaintiff's decedent, to believe that Neurontin was effective in the treatment of the causes and symptoms of pain and migraines.

133. That at all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by defendants was a proximate cause of the death of plaintiff's decedent.

134. That at all times hereinafter mentioned, plaintiff's decedent did not contribute to his death by reason of any negligence or culpable conduct on his part.

135. That as a result of the aforesaid occurrence, the injuries sustained by and the death of plaintiff's decedent resulting therefrom, plaintiff's decedent's beneficiaries suffered extensive monetary and pecuniary losses and other compensatory damages, including, but not limited to, (A) damages for loss of love, affection, care, service, companionship, society, training, and consortium; (B) compensation for reasonably expected loss of (i) income of the decedent, and (ii) services, protection, care and assistance provided by the decedent; (C) expenses for the care, treatment and hospitalization of the decedent incident to the injury resulting in death; and (D) reasonable funeral expenses. In addition, plaintiff was deprived of a chance for effective and/or successful treatment.

136. That by reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks all damages available under applicable laws, including but not limited to, exemplary damages against defendants in an amount to be determined upon the trial of this matter.

## **COUNT II**

### **BREACH OF WARRANTY**

137. Plaintiff repeats and reiterates the allegations previously set forth herein.

138. That at all times hereinafter mentioned, upon information and belief, defendants, by directly and indirectly advertising, marketing and promoting Neurontin for

the treatment of pain and migraines and by placing this drug in the stream of commerce knowing that Neurontin would be prescribed for the treatment of pain and migraines in reliance upon the representations of defendants, expressly warranted to all foreseeable users of this drug, including plaintiff's decedent, that Neurontin was safe and effective for the treatment of pain and migraines.

139. That defendants impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Neurontin to all foreseeable users, including plaintiff's decedent, that Neurontin was safe and effective for the purposes for which it had been placed in the stream of commerce by defendants, including for the treatment of pain and migraines, and that Neurontin was reasonably safe, proper, merchantable and fit for the intended purposes, including for the treatment of pain and migraines.

140. That at all times hereinafter mentioned, plaintiff's decedent relied upon the aforesaid express and implied warranties by defendants.

141. That at all times hereinafter mentioned, plaintiff's decedent's use of Neurontin prior to and up to the time of the above-described incident was consistent with the purposes for which defendants directly and indirectly advertised, marketed and promoted Neurontin, and plaintiff's decedent's use of Neurontin was reasonably contemplated, intended and foreseen by defendants at the time of the distribution and sale of Neurontin by defendants, and, therefore, plaintiff's decedent's use of Neurontin was within the scope of the above-described express and implied warranties.

142. Defendants breached the aforesaid express and implied warranties because Neurontin was not safe and effective for the treatment of pain and migraines

and because plaintiff's decedent's use of Neurontin for the treatment of pain and migraines caused or contributed to the incident described herein.

143. Plaintiff's decedent gave appropriate notice to defendants of the breach of the aforesaid express and implied warranties or such notice was otherwise excused.

144. That by reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks all damages available under applicable laws, including but not limited to, exemplary damages against defendants in an amount to be determined upon the trial of this matter.

### **COUNT III**

#### **STRICT LIABILITY**

145. Plaintiff repeats and reiterates the allegations previously set forth herein.

146. That at all times hereinafter mentioned, the drug Neurontin was not suited for the treatment of pain and migraines and was not safe and effective for the treatment of pain and migraines even though defendants directly and indirectly advertised, marketed and promoted Neurontin for that purpose.

147. That at all times hereinafter mentioned, the drug Neurontin was not safe and was not suited for the purposes for which defendants, directly and indirectly, advertised, marketed and promoted the drug at the time defendants designed, manufactured, distributed and sold the drug and placed the drug in the stream of commerce.

148. That at all times hereinafter mentioned, upon information and belief, defendants assumed a strict products liability to users and to persons using Neurontin, including plaintiff's decedent, who sustained injuries, harm and damages by reason of the use of Neurontin for purposes directly and indirectly advertised, marketed, and promoted by defendants, including for the treatment of pain and migraines.

149. That by reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks all damages available under applicable laws, including but not limited to, exemplary damages against defendants in an amount to be determined upon the trial of this matter.

#### **COUNT IV**

#### **FRAUDULENT MISREPRESENTATION**

150. Plaintiff repeats and reiterates the allegations previously set forth herein.

151. Defendants materially misrepresented material facts concerning the safety and effectiveness of Neurontin in the treatment of pain and migraines.

152. Defendants' affirmative misrepresentations include but are not limited to the acts set forth in the following paragraphs.

153. In or about 1993, defendants submitted a new drug application (NDA) for approval of a drug called Neurontin (also known by the chemical name "gabapentin"), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3(h)(4) and (5). In that application, defendants sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the

treatment of partial seizures with and without secondary generalization in adults with epilepsy. On or about December 30, 1993, the FDA approved Neurontin for that specific use only. Because defendants had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than that approved use.

154. Commencing in at least June of 1995 and continuing through at least the date of this incident, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD), and migraine headaches, among other uses.

155. Defendants did not file a new NDA seeking FDA approval for any of these unapproved uses at any time prior to the date of this incident.

156. Defendants conducted evaluations of the market potential for certain of the unapproved uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

157. In or about the fall of 1995, defendants' Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including plans for conference calls on pain and a pain consultant meeting.

158. Certain defendants' annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies and tactics for increasing sales of the unapproved uses of the drug. The marketing plans budgeted for and funded these tactics.

159. Commencing in early 1995 and continuing at least through the date of this incident, defendants determined not to seek FDA approval for certain unapproved uses.

160. In or about April and May of 1995, defendants performed a marketing assessment of proposed psychiatric indications for Neurontin. In that marketing assessment, defendants forecast potential revenue from Neurontin for bipolar disorder and anxiety treatment under two scenarios: with and without FDA approval. Defendants' Neurontin Development Team and New Product Committee reviewed the potential psychiatric uses and concluded that the defendants would not seek approval to promote and sell the drug for these unapproved uses.

161. In or about July of 1995, defendants' assessment of Neurontin's market potential for neuropathic pain was distributed to defendants' Neurontin Development Team and to defendants' Vice President for marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to the FDA for approval.

162. One of the principal factors defendants considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that defendants were developing. Defendants expected

this new drug would be approved by the FDA not only for epilepsy but also for a variety of uses beyond Neurontin's approved use.

163. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in defendants' original NDA approval for Neurontin. If defendants sought and obtained approval for any of the unapproved uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those unapproved uses. Defendants were concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

164. Commencing about June of 1995 until at least the date of this incident, by certain conduct described in greater detail below, defendants promoted the sale and use of Neurontin for certain conditions other than the approved use.

165. In October 1995, a member of defendants' Epilepsy Disease Team circulated a memorandum to a group including other senior members of defendants' Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 of defendants' sales representatives for whom data was available in a two-month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

166. On or about July 10, 1996, defendants' sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

167. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales representatives could present lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

168. Defendants employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following occasions, which are not all-inclusive, defendants' medical liaisons promoted Neurontin for unapproved uses:

(a) In or about June of 1996 defendants' sales representative requested that defendants' medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for unapproved uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of unapproved uses.

(e) After the presentation, defendants' Medical Director praised the event as "another great example of use of the medical liaisons" and an area business manager called it an "outstanding utilization of . . . one of the medical affairs liaisons."

169. Defendants organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida, on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to unapproved uses of Neurontin.

170. Defendants invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, defendants paid for accommodations and meals for the invited doctors and their spouse or guest, and paid an honorarium to each of the doctor attendees.

171. Among the presentations made to the physicians in attendance was one relating to unapproved uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

172. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol and pain.

173. On or about May 8, 1996, following the Jupiter Beach conference, defendants circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations.

174. From August 1-5, 1996, defendants organized an "advisory board meeting," in Atlanta, Georgia, in conjunction with the 1996 Summer Olympics. Defendants expressly instructed several of the physician speakers to address some of the unapproved uses.

175. During that meeting, defendants hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. Defendants already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on defendants' behalf at prior meetings.

176. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

177. On or about March 1, 1996, defendants sponsored a teleconference moderated by defendants' employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

178. In or about May, 1996, defendants' Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

179. Defendants hosted dozens of "consultants" meetings between late 1995 and 1997 in which the "consultants" received payments and gratuities as well as presentations on "off-label" Neurontin use designed to change the physicians' prescription writing habits. Such consultants' meetings included, but were not limited to the following:

<u>Topic</u>	<u>Location</u>	<u>Dates</u>
Mastering Epilepsy	La Costa Resort, CA	July 20-23, 1995
Mastering Epilepsy	Santa Fe, NM	Nov. 16-19, 1995
Neurontin Consultants Conference	Marco Island, FL	Feb. 2-4, 1996
Pediatric Epilepsy	Hutchinson Island, FL	Feb. 9-11, 1996
Mastering Epilepsy Science	Walt Disney World, FL	Feb. 22-25, 1996
Pediatric Epilepsy	Hutchinson Island, FL	Mar. 8-10, 1996
Mastering Epilepsy	Ritz Carlton, Aspen, CO	Apr. 18-21, 1996
Affective Disorders in Psychiatry	Marco Island, FL	Apr. 20, 1996
Neurological Consultants (discussed previously)	Jupiter Beach, FL	Apr. 19-21, 1996
Affective Disorder Consultants Conference	Southern Pines, NC	Apr. 27, 1996
Neuropathic Pain Conference	Palm Beach, FL	May 11, 1996
Regional Consultants Conference	Ritz Carlton, Boston, MA	May 10-11, 1996
Epilepsy Management Advisors Meeting	Sheraton Grande, Torrey Pines, La Jolla, CA	June 21-23, 1996
Epilepsy Management	Rancho Bernardo, CA	June 28-30, 1996
Use of Anti-Convulsants in Psychiatric Disorders	Short Hills, NJ	Oct. 18-19, 1996

Non-epileptic Uses of Neurontin                      Longboat Key, FL                      Nov. 6, 1996  
Neurological Conditions Conference                      Ritz Carlton, Atlanta, GA                      Sep. 27-28, 1997  
Other "consultants" meetings took place at Charleston, SC, Coconut Grove, FL, Naples, FL, Memphis, TN, Louisville, KY, Washington, DC, Aspen, CO, and other places.  
Hundreds, if not thousands, of physicians received kickbacks to attend these events.

180. Defendants rewarded doctors for their advocacy of Neurontin by paying them honoraria for lending their names to scientific articles which were actually prepared and written by third parties retained by defendants. In 1996, defendants retained AMM/ADELPHI, Ltd. and Medical Education Systems, Inc., to prepare no less than twenty (20) articles for publication in various neurology and psychiatry journals. Most of these articles concerned "off-label" usage of Neurontin and were generated so that defendants could completely control the publications distributed pursuant to its "publications strategy." The content of these articles were actually written by non-physician technical writers retained by defendants and defendants had the right to control the content of all the articles. Defendants paid all expenses in connection with the creation of these publications.

181. Defendants also founded a speakers' bureau, another method of making large and numerous payments to physicians who recommended Neurontin for "off-label" uses, together with teleconferences, dinner meetings, consultants meetings, educational seminars, and other events.

182. Defendants utilized medical liaisons who were provided with new company slides that detailed methods to increase "off-label" use of Neurontin, including the following:

Reflex sympathetic dystrophy (RSD)

Peripheral neuropathy

Diabetic neuropathy

Trigeminal neuralgia

Post-herpetic neuralgia

Essential tremor

Restless leg syndrome (RLS)

Attention deficit disorder (ADD)

Periodic limb movement disorder

Migraine

Bipolar disorder

Amyotrophic lateral sclerosis (ALS/Lou Gehrig's Disease)

Drug or alcohol withdrawal seizures

183. The following enumerated misrepresentations, which are not intended to be all-inclusive, relating to "off-label" usage of Neurontin were routinely made to physicians with the knowledge and consent of marketing personnel of defendants:

a. *Bipolar Disorder.* Medical liaisons informed psychiatrists that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder indicated ninety percent (90%) response rate when Neurontin was started at 900 mg/day dosage and increased to a dosage of 4800 mg/day. No such results existed.

b. *Peripheral Neuropathy, Diabetic Neuropathy, and Other Pain Syndromes.* Medical liaisons stated that clinical trials demonstrated that Neurontin was highly effective in the treatment of various pain syndromes and that a ninety percent

(90%) response rate in the treatment of pain was being reported. No such body of evidence existed. Defendants continued to claim that physicians should use Neurontin at substantially higher doses than indicated by the labeling. Indeed, although medical liaisons routinely claimed Neurontin to be effective as monotherapy, in 1997 the FDA refused to find Neurontin as a safe and effective monotherapy.

c. *Reflex Sympathetic Dystrophy ("RSD")*. Medical liaisons informed physicians that extensive evidence demonstrated the efficacy of Neurontin in the treatment of RSD. The only such evidence that existed was anecdotal reports of nominal scientific value.

d. *Attention Deficit Disorder ("ADD")*. Medical liaisons were instructed to inform pediatricians that Neurontin was effective for the treatment of ADD. No data, other than occasional anecdotal evidence, supported this claim.

e. *Restless Leg Syndrome ("RLS")*. RLS was another condition where defendants' medical liaisons were trained to refer to a growing body of data relating to the condition, when no scientific data existed.

f. *Trigeminal Neuralgia*. Although medical liaisons represented that Neurontin could treat trigeminal neuralgia, again no scientific data supported this claim with the exception of occasional anecdotal reports. No data demonstrated that Neurontin was as effective as currently available pain killers, most of which were inexpensive.

g. *Post-Herpetic Neuralgia ("PHN")*. Medical liaisons were trained to tell physicians that seventy-five percent (75%) to eighty percent (80%) of all PHN

patients were successfully treated with Neurontin. Once again, no clinical trial data supported such a claim.

h. *Essential Tremor Periodic Limb Movement Disorder ("ETPLMD").*

Medical liaisons were trained to allege that Neurontin was effective in the treatment of these conditions. No scientific data supported such claims with the exception of anecdotal reports of nominal scientific value.

i. *Migraine.* Claims that Neurontin was effective in the treatment of migraine headaches were made by the medical liaisons and were supposedly based on early results from clinical trials. Although pilot studies had been such suggested and undertaken, no early results of clinical trials existed to support these claims. Once again, any data relating to treatment of migraines was purely anecdotal and of nominal scientific value. Most of the case reports were either created or sponsored by defendants.

j. *Drug and Alcohol Withdrawal Seizures.* Medical liaisons suggested that Neurontin be used in the treatment of drug and alcohol withdrawals despite the lack of any data supporting Neurontin as an effective treatment for these conditions.

184. Defendants sponsored a 1998 study, which was scientifically valid, conducted at the Harvard Bipolar Research Program, which concluded that patients receiving Neurontin did worse than those on sugar pills, but even though defendants were fully aware of these results from the tests which they sponsored, defendants did not publish the results until two years later after a substantial number of physicians had already been induced to prescribe Neurontin and a substantial number of patients had already been induced to take Neurontin.

185. At each of the presentations known to the plaintiff concerning Neurontin on pain, at least one of the presenters expressly stated or implied that Neurontin was effective for the treatment of pain. A representative statement was made by Dr. David Longmire, a participating physician, at the Jupiter Beach Consultants Meeting in April 1996 when he stated that Neurontin was effective for the treatment of pain. Dr. Longmire repeated that statement at a May 1996 Consultants Meeting at the Ritz Carlton in Boston. Another physician participant, Dr. Steven Schacter, made a similar statement at the May 1996 meeting when he stated that "pain specialists are finding that low dosages of Neurontin are effective." Comparable statements were made by another physician participant, Dr. Bruce Nicholson, in April 1996 at the Jupiter Beach Consultants Meeting, in May 1996 at the Boston Ritz Carlton Consultants Meeting, and in June 1996 at a Philadelphia Consultants Meeting. Upon information and belief, similar statements were made at all events presented by defendants that discussed Neurontin's use for pain indications. These events include, but are not limited to the following events:

<u>Topic</u>	<u>Date</u>	<u>Location</u>
Neurontin Consultants Meeting	Apr. 19-21, 1996	Jupiter Beach, FL
Neurontin Consultants Meeting	May 3-4, 1996	Philadelphia, PA
Neurontin Consultants Meeting	May 10-11, 1996	Boston, MA
Advisory Board Meeting	Apr. 14-16, 2000	Grand Wailea Resort Hotel & Spa, Maui, HI
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ

New Treatment Options for the Management of Pain: The Role of Anticonvulsants	Apr. 2000	Four Seasons Irving, TX
Advisory Board Meeting	May 26, 2000	Disney Yacht Club Orlando, FL
New Directions in the Understanding and Treatment of Pain	Mar. 24, 2001	Plaza Hotel New York, NY
New Directions in the Understanding and Treatment of Pain	Mar. 2-3, 2001	Hilton Novi Detroit, MI
New Directions in the Understanding and Treatment of Pain	May 4-5, 2001	Westin Galleria Houston, TX
New Directions in the Understanding and Treatment of Pain	Feb. 9-10, 2001	Harbor Court Hotel Baltimore, MD
New Directions in the Understanding and Treatment of Pain	Mar. 9-10, 2001	Fairmont Kansas City Kansas City, MO
New Directions in the Understanding and Treatment of Pain	May 11-12, 2001	Peabody Memphis Memphis, TN
New Directions in the Understanding and Treatment of Pain	Mar. 16-17, 2001	Fairmont San Francisco San Francisco, CA
Advisory Board Meeting	June 16-18, 2000	Westin Resort Hilton Head, SC
New Directions in the Understanding and Treatment of Pain	May 18-19, 2001	Sheraton Universal City Universal City, CA
New Directions in the Understanding and Treatment of Pain	May 18-19, 2001	Miami Biltmore Miami, FL
New Directions in the Understanding and Treatment of Pain	Mar. 23-24, 2001	Ritz Carlton New Orleans New Orleans, LA
New Directions in the Understanding and Treatment of Pain	Mar. 23-24, 2001	Sheraton Music City Nashville, TN
New Directions in the Understanding and Treatment of Pain	Mar. 30-31, 2001	Ritz Carlton St. Louis St. Louis, MO

New Directions in the Understanding and Treatment of Neuropathic Pain      Oct. 9-11, 1998      Madeira, Portugal

186. At events produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of restless leg syndrome or RSD. Events presented by defendants that discussed Neurontin's use as a treatment for restless leg syndrome or RSD include, but are not limited to, the following event:

<u>Topic</u>	<u>Date</u>	<u>Location</u>
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

187. At events produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of bipolar disorder. Events presented by defendants that discussed Neurontin's use as a treatment for bipolar disorder include, but are not limited to, the following events:

<u>Topic</u>	<u>Date</u>	<u>Location</u>
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess, Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire Beverly Hills, CA
Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place, New Orleans, LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ

1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrazia New York, NY
The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 1998	Barcelona, Spain

188. At events produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of social phobia. Events presented by defendants that discussed Neurontin's use as a treatment for social phobia include, but are not limited to, the following events:

<u>Topic</u>	<u>Date</u>	<u>Location</u>
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess, Scottsdale, AZ
Merritt-Putnam Speakers Bureau Perspectives in the Current Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire Beverly Hills, CA
Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place, New Orleans, LA
Merritt-Putnam Speakers Training Advanced Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrazia New York, NY

The Use of Anticonvulsants in Psychiatry      Oct. 23-25, 1998      Barcelona, Spain

189. Without favorable results from a well-designed panic disorder clinical trial that established Neurontin's efficacy for that condition, Parke-Davis had no reasonable scientific basis for claiming that Neurontin was effective in treating panic disorder. Nonetheless, at events produced by defendants, physician participants routinely stated that Neurontin was effective for the treatment of panic disorder. Events presented by defendants that discussed Neurontin's use as a treatment for panic disorder include, but are not limited to, the following events:

<u>Topic</u>	<u>Date</u>	<u>Location</u>
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Parke-Davis Speakers Bureau Meeting	Jan. 21-23, 2000	Fairmont Scottsdale Princess, Scottsdale, AZ
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire Beverly Hills, CA
Merritt-Putnam Speakers Bureau	Apr. 7-9, 2000	Wyndham New Orleans at Canal Place, New Orleans, LA
Merritt-Putnam Speakers Training Perspectives in the Management of Neurological and Mood Disorders	Apr. 28-30, 2000	Enchantment Resort Sedona, AZ
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Maison Robert Boston, MA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Sunset Grill Nashville, TN
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 16, 1998	Pescatore Fish Cafe Seattle, WA

1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Patrick's Bayside Bistro St. Pete's Beach, FL
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 17, 1998	Heathman Hotel Portland, OR
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Downtown Club Philadelphia, PA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Morton's of Chicago Buckhead, Atlanta, GA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 18, 1998	Huntington Hotel San Francisco, CA
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Brass Elephant Baltimore, MD
1998 CME Psychiatry Dinner Meeting and Teleconference Series	Mar. 19, 1998	Ristorante DeGrezia New York, NY
The Use of Anticonvulsants in Psychiatry	Oct. 23-25, 199	Barcelona, Spain

190. On September 13, 1996, Parke-Davis submitted a supplemental NDA to approve Neurontin as monotherapy for partial seizures. The FDA determined the application to be non-approvable on August 26, 1997, because of insufficiency of evidence of Neurontin's effectiveness. The FDA noted that Clinical Study 945-82 failed to yield evidence of effectiveness. Parke-Davis did not make public that its application for monotherapy had been denied. Representative events at which defendants continued to make presentations that Neurontin was effective for monotherapy without disclosing that the FDA had denied its application for a monotherapy indication include, but are not limited to, the following events:

<u>Topic</u>	<u>Date</u>	<u>Location</u>
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

Monotherapy Speakers Bureau  
Meeting

September 1997

La Quinta Resort  
Palm Springs, CA

191. Thereafter, pursuant to marketing strategies and tactics developed by Parke-Davis and defendants, defendants regularly presented programs in which physician participants touted Neurontin as being effective for the treatment of migraine. Events where such presentations were made include, but are not limited to, the following events:

<u>Topic</u>	<u>Date</u>	<u>Location</u>
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX
Gabapentin in the Management of Migraine	May 25, 1996	Short Hills, NJ

192. Notwithstanding the FDA's refusal to increase the maximum approved dosage of Neurontin and its finding that no clinical evidence supported Neurontin's efficacy at dosages greater than 1800 mg per day, defendants presented numerous programs where physician participants asserted that Neurontin was effective and safe at dosages above 1800 mg. All such representations were false and misleading. Additionally, at these presentations the physician participants did not disclose the clinical trial evidence that demonstrated that there was no dose response above 1800 mg per day. Defendants' failure to provide this information was a violation of defendants' duties to provide fair and balanced information, and made any prior representations about use of Neurontin at dosages greater than 1800 mg per day false and misleading. In addition to the events identified above, other events where these false and misleading statements were made include, but are not limited to, the following events:

<u>Topic</u>	<u>Date</u>	<u>Location</u>
Advisory Board Meeting on Neurontin	Feb. 4-6, 2000	Royal Sonesta New Orleans, LA
Merritt-Putnam Speakers Bureau Current Perspectives in the Understanding of Neurobehavioral Disorders	Mar. 24-26, 2000	Four Seasons Regent Beverly Wilshire Beverly Hills, CA
Advisory Board Meeting	Mar. 29, 2000	Hyatt Regency Hotel San Antonio, TX

193. On or about June 29, 2001, the FDA Division of Drug Marketing, Advertising and Communications (DDMAC) advised defendants that through routine monitoring and surveillance, the DDMAC has identified a slim jim (ID #NSJ5095A1) for Neurontin that is misleading and in violation of the FDCA and applicable regulations, in that this slim jim misleadingly claims improvement in quality of life (QOL) parameters based on the Neurontin Evaluation of Outcomes in Neurological Practice (NEON) study, that among other QOL parameters, the misleading presentation includes improvement in social limitations, memory difficulties, energy level, and work limitations, and that the NEON study is not considered to be substantial evidence for claims of QOL improvements because it is not a controlled study.

194. On or about July 1, 2002, the DDMAC advised defendants that through routine monitoring and surveillance, the DDMAC has identified a model (#NE 102254) for Neurontin (gabapentin) that is in violation of the FDCA and applicable regulations because it makes representations about Neurontin which are false or misleading, in that this suggestion of proof of the mechanism of action is false and contrary to the language in the approved product labeling that states "[t]he mechanism by which gabapentin [Neurontin] exerts its anticonvulsant action is unknown," and that, furthermore, the full

presentation of the areas of the human brain accompanied by purported "Mechanism of Action" and the prominent display of the name "Neurontin" is misleading because it suggests that Neurontin is useful for a broader range of central nervous system conditions than has been demonstrated by substantial evidence.

195. From July 1995 through at least August 5, 2002, defendants engaged in a marketing program to promote the use of Neurontin, and to induce physicians to prescribe Neurontin, for medical conditions for which the FDA had not approved Neurontin to be used (i.e., "unapproved" or "off-label" uses). That program included: (a) illegally promoting the sale and use of Neurontin for a variety of conditions other than the one condition for which its use was approved by the FDA and for which defendants had not performed the required FDA testing or established safety and efficacy, in violation of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 331, et seq.; (b) offering and paying illegal remuneration to doctors, either directly or through third parties, to induce them to promote and prescribe Neurontin for off-label uses, in violation of the federal Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b); and (c) making and/or disseminating false statements in presentations and marketing literature sales personnel provided to doctors concerning, among other things, the uses for which the FDA had approved Neurontin, the conditions for which the use of Neurontin was otherwise medically accepted and/or the existence of adequate evidence of the safety and efficacy for such use.

196. In order to avoid sanction and regulation by the FDA, defendants' off-label marketing scheme depended on their concealment of their involvement in off-label promotion of Neurontin, and to make it appear to the public that defendants did not have

any hand in any discussions of off-label use. In addition, defendants performed off-label promotion in the semblance of legitimate consultants' meetings, continuing education seminars, journal articles and medical education events. Also, defendants' involvement was hidden because defendants hid their financial connections between the participating physicians and used the vendor participants as payment intermediaries. These activities and others described herein concealed defendants' off-label promotional activities, and plaintiff's decedent could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Much of the scheme to this day remains concealed by defendants.

197. In May 2003, the details of defendants' interactions with the other participants were disclosed through the filing by a former medical liaison, Dr. David Franklin, of previously sealed materials in opposition to defendants' motion for summary judgment in the qui tam action. This "off-label" promotion scheme remained hidden until, the United States District Court for the District of Massachusetts Court unsealed Dr. Franklin's Amended Complaint in the qui tam case by in April or May 2002.

198. In addition, defendants fraudulently concealed information and documents concerning the safety and efficacy of Neurontin, in particular, information and documents indicating that the ingestion of Neurontin for off-label uses and/or at high dosages, may cause suicidal ideations, gestures and acts.

199. Any applicable statutes of limitation have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiff's decedent and other members of the public who were prescribed and ingested Neurontin for off-label uses have been kept in ignorance of vital information essential to the pursuit

of these claims, without any fault or lack of diligence on their part, and could not reasonably have discovered the fraudulent nature of defendants' conduct, and information and documents concerning the safety and efficacy of Neurontin, in particular, information and documents indicating that the ingestion of Neurontin for off-label uses and/or at high dosages, may cause suicidal ideations, gestures and acts. Accordingly, defendants are estopped from relying on any statute of limitations to defeat any of plaintiff's claims.

200. Similarly, due to defendants' fraudulent concealment of the aforesaid documents and/or information, the scientific and/or medical community was not apprised of vital information concerning safety and efficacy of the drug Neurontin. Furthermore, due to the aforesaid allegations, plaintiff may rely on the discovery rule in pursuit of this claim.

201. On information and belief, defendants' "off-label" promotion scheme continued after the filing of Dr. Franklin's whistleblower complaint and still continues. For example, through the third quarter of 2002, there were no published scientific studies to support Neurontin's use for a wide variety of diseases that it is being prescribed for including anxiety disorder, attention deficit disorder, bipolar disorder, cluster headache, depression, dosages in excess of 1800 mg per day and many other disorders that physicians are now prescribing Neurontin for that are "off-label." Despite this lack of scientific evidence, Neurontin sales for these and other "off-label" uses have steadily increased, to the point that, according to an article published in the December 1, 2003 issue of Medical Marketing & Media, 90% of Neurontin sales are for "off-label" use. No other drug in the United States has such a high percentage of "off-label" use.

The same article estimates that \$1.8 billion worth of Neurontin has been sold for "off-label" uses. This increase in sales, and the repeated and increased prescription of Neurontin for "off-label" uses, without any supporting scientific studies that would be prompting such use, cannot be a random event and could not occur without continuing "off-label" promotion by defendants' sales force.

202. As a result of the activities described above, many of which continue to occur after Dr. Franklin filed his whistleblower suit, physicians were inundated with false information about Neurontin. As a result, they continue to prescribe Neurontin for "off-label" uses for which there is no reliable scientific support.

203. On information and belief, Pfizer has a company-wide practice of marketing "off-label" indications. "Off-label" marketing plans exist for Cox 2 inhibitors and, on information and belief, also exist for Neurontin.

204. This continuing course of conduct is evidenced in part by the staggering growth of Neurontin sales for "off-label" uses. Because there are no valid scientific studies supporting such use, a reasonable inference is that the use results from past and continuing promotional efforts by defendants. This clear and unavoidable conclusion follows from observations regarding the ongoing extent of prescriptions written for "off-label" Neurontin use.

205. First, from the perspective of overall Neurontin sales, "off-label" usage of Neurontin has actually increased during the years since 1999; in recent years, "off-label" prescriptions for Neurontin have exceeded 90% of all sales and, in some months, it appears that approved indication usage is negligible.

206. Second, although Neurontin is prescribed for scores of "off-label" indications, since 1999 the types of "off-label" usage continue to be weighted in the precise areas where defendants focused their illegal marketing efforts: bipolar disorder, peripheral neuropathy, migraine, etc.

207. Third, these focus treatment areas of continuing unapproved usage are subject to very intense competition between therapeutic substitutes (other drugs or treatments). Indeed, because manufacturers' incremental cost for drugs in these areas is very small (e.g., only pennies to manufacture an additional pill), manufacturers compete aggressively for market share by spending huge amounts of money for marketing, promotional and sales activities. If any company was to simply pack its tent and discontinue programmatic promotional effort in any therapeutic arena, significant loss of overall sales within that diagnosis regime would certainly occur. For Neurontin, no such dip in overall sales, let alone any significant drop, has occurred.

208. Fourth, Pfizer, like most branded drug companies, monitors the relationship of its sales to its promotional efforts in very short timeframe; Pfizer would be concerned about a drop in sales within a certain therapeutic regime not after a year look-back, or even a quarterly look-back, but over just weeks. The persistent maintenance of high Neurontin sales within multiple, targeted areas for "off-label" promotion over a period of years defies the conclusion that any significant backing away on the marketing, sales or promotion of Neurontin to each of those approved therapeutic areas.

209. For example, sales of Neurontin for the treatment of bipolar disorder have steadily increased since its introduction. This increase is a direct result of defendants' sales representatives recommending to doctors its use for this purpose and their distribution of unapproved promotional materials. These promotional efforts did not stop in 1999, but continued thereafter. There are no valid scientific studies that support Neurontin's use for bipolar disorders. Dr. C. Seth Landefeld has submitted an expert opinion in the Franklin litigation that a review of Drugdex for Neurontin, as of the end of August 2002, reveals "no published scientific studies to support Neurontin's use for . . . bipolar disorder." As a result, tens of thousands of patients who need help and could use other drugs whose effectiveness has been established, were given and are being given Neurontin. These prescriptions for this purpose are still being written and as a direct result of defendants' pre-2000 illegal promotional activities and post-2000 illegal promotional activities.

210. Likewise, sales of Neurontin for pain, ALS, attention deficit disorder, depression and dosages in excess of 1800 mg per day, are also increasing without any scientific evidence supporting use of Neurontin for such indications. Again, as noted by Dr. Landefeld, as of the end of the third quarter of 2002 "there were no published scientific studies to support Neurontin's use for" any of these indications or in an increased dose.

211. Overall, "off-label" sales of Neurontin have steadily increased since 1998, and from 2000 to the present have consistently remained at 93% to 94% of all sales. Actual sales for approved uses has declined. Given the absence of scientific support for such uses, the genesis for those sales can only be past and continuing efforts by defendants to promote "off-label" use.

212. Defendants made additional fraudulent misrepresentations as to the safety and effectiveness of Neurontin, which are not detailed herein but will be determined in discovery.

213. Defendants affirmatively and fraudulently misrepresented that Neurontin was safe and effective in the treatment of pain and migraines when, in actuality, Neurontin was ineffective in treating such condition and instead influenced users to engage in self-destructive behavior.

214. Defendants affirmatively and fraudulently misrepresented that Neurontin was safe for human consumption in general, when in actuality, Neurontin influenced users to engage in self-destructive behavior.

215. Defendants knew that Neurontin was not safe and effective in the treatment of pain and migraines and that Neurontin was not safe for human consumption in general because such drug influenced users to engage in self-destructive behavior.

216. Defendants knew that physicians, health care providers, and mental health care providers would justifiably rely upon defendants' misrepresentations in prescribing Neurontin in the treatment of pain and migraines and in prescribing Neurontin for human consumption in general for the treatment of illnesses and medical and mental conditions and that the public, including persons such as plaintiff's decedent, would justifiably rely upon defendants' misrepresentations in using Neurontin as prescribed by physicians, health care providers and mental health care providers in the treatment of pain and migraines and for other prescribed uses.

217. Plaintiff's decedent justifiably relied upon defendants' misrepresentations and, accordingly, consumed Neurontin as prescribed by his physician in the treatment of pain and migraines.

218. By reason of plaintiff's decedent's consumption of Neurontin in justifiable reliance upon defendants' fraudulent misrepresentations, plaintiff's decedent sustained injuries and was caused to commit suicide.

219. That by reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

#### **COUNT V**

#### **VIOLATION OF DELAWARE CONSUMER FRAUD ACT**

220. Plaintiff repeats and reiterates the allegations previously set forth herein.

221. Defendants acted, used and employed deception, unfair and deceptive

acts and practices, fraud, false pretenses, false promises, misrepresentations, concealment, suppression and omission of material facts with intent that physicians and medical providers rely upon such concealment, suppression and omission, and for the purpose of influencing and inducing physicians and medical providers to prescribe Neurontin, at excessively high dosages, for unapproved "off-label" uses, including treatment for pain and migraines, to patients/consumers such as plaintiff's decedent, and causing such patients/consumers to purchase, acquire and use Neurontin, at high dosages, for unapproved "off-label" uses, including treatment for pain and migraines, as prescribed by their physicians and medical providers, in connection with the sale and advertisement of the drug Neurontin, in violation of 6 Del. C. §§ 2513.

222. By reason of defendants' acts, uses and employment of deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts, reasonable patients/consumers acting reasonably, such as plaintiff's decedent, were caused to commit suicide.

223. That by reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks punitive and exemplary damages against defendants in an amount to be determined upon the trial of this matter.

**COUNT VI**

**SURVIVAL ACTION**

224. Plaintiff repeats and reiterates the allegations previously set forth herein.

225. That at the time of the incident and during plaintiff's decedent's consumption of Neurontin prior to and until the time of his death, plaintiff's decedent suffered suicidal ideations and apprehension of death during a period of time leading up to the actual commission of suicide.

226. That for a period of time leading up to and at the time of the aforesaid suicide, plaintiff's decedent lived and was suffering excruciating mental anguish, severe pain and suffering.

227. That by reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages recoverable pursuant to 10 Del. C. §§ 3701 and 3724, in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, plaintiff seeks all damages available under applicable laws, including but not limited to, exemplary damages against defendants in an amount to be determined upon the trial of this matter.

228. Defendants are liable for all economic damages sustained by the estate of DANA ANDREW TILLEY.

229. Defendants are liable for all funeral expenses, medical special damages and any other out of pocket costs sustained by the plaintiff.

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OFFICES

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Form No. 5 - Short Certificate

EFiled: Jul 7 2006 2:01PM  
Transaction ID 11728078

State of Delaware

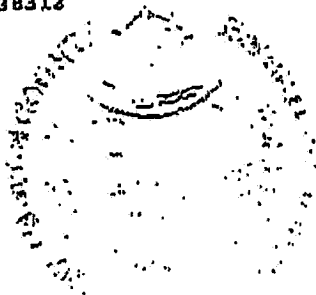


NEW CASTLE COUNTY, SS.

I, Diane Clarke Streett, Register of Wills for New Castle County, State of Delaware, do hereby certify that on the 5th day of July, 2006, Letters of Administration upon the Estate of Dana Andrew Tilley, deceased, were in due form of law granted unto Kelly A. Tilley, who is/are now the Personal Representative(s) upon said estate, to all whose acts, as such, full faith and credit are to be given. I do further certify that the Personal Representative(s) is/are invested with full authority to direct and execute the transfer, assignment, or reissue of any stocks, bonds, documents of title, money in banks, or other securities of any incorporated company, being owned and held by the decedent at the time of his/her death and now constituting part of his/her personal estate. This appointment is still in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand and official seal, this 5th day of July, 2006.

File # 138312



Register of Wills

NOT VALID WITHOUT IMPRESSED SEAL

TOTAL P.03

WHEREFORE, plaintiff, KELLY A. TILLEY, respectfully requests that judgment be entered against defendants, PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC, jointly and severally for compensatory, special and exemplary damages, the cost of this action, and pre- and post-judgment interest, along with any additional relief that this Court may deem proper.

RAMMUNO, RAMUNNO & SCERBA, P.A.

By: /s/ L. VINCENT RAMUNNO, ESQ.  
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Attorneys for Plaintiff Kelly A. Tilley

DATED: July 7, 2006

Of Counsel:

Andrew G. Finkelstein, Esq.  
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Newburgh, NY 12550  
(800) 634-1212

EFiled: Jul 7 2006 2:01PM  
Transaction ID 11728078



**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE  
IN AND FOR NEW CASTLE COUNTY**

KELLY A. TILLEY, as Personal  
Representative of the Estate of  
DANA ANDREW TILLEY, Deceased,  
  
Plaintiff,

vs.

PFIZER INC., PARKE-DAVIS,  
a division of Warner-Lambert Company  
and Warner-Lambert Company LLC,  
WARNER-LAMBERT COMPANY and  
WARNER-LAMBERT COMPANY LLC,  
  
Defendants.

Civil Action No. 06C-07-046 RRC

**NON-ARBITRATION CASE**

**JURY OF TWELVE DEMANDED**

**CERTIFICATE OF VALUE**

The undersigned hereby certifies in my opinion that the value of this  
claim does exceed \$100,000.

RAMMUNO, RAMUNNO & SCERBA, P.A.

By: /s/ L. VINCENT RAMUNNO, ESQ.  
L. VINCENT RAMUNNO, ESQ. (#594)  
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Attorneys for Plaintiff Kelly A. Tilley

DATED: July 7, 2006

EFiled: Jul 7 2006 2:01PM  
Transaction ID 11728078



# EXHIBIT "A"

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UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

Plaintiff,

v.

WARNER-LAMBERT COMPANY LLC

Defendant.

Crim. No.

Violations:  
Title 21, United States  
Code Sections 331(a),  
331(d), 352(f)(1),  
and 355(a)

INFORMATION

THE UNITED STATES ATTORNEY FOR THE DISTRICT OF MASSACHUSETTS  
CHARGES THAT:

GENERAL ALLEGATIONS

At all times material to this Information, unless otherwise alleged:

BACKGROUND

1. WARNER-LAMBERT COMPANY LLC (hereinafter "WARNER-LAMBERT"), was a corporation operating and existing under the laws of the State of Delaware. Its principal place of business was Morris Plains, New Jersey. WARNER-LAMBERT's Parke-Davis Division was engaged in, among other things, the development, manufacture, promotion, sale, and interstate distribution of prescription drugs intended for human use in the United States. WARNER-LAMBERT's pharmaceutical manufacturing facilities were located in Puerto Rico, from which it shipped products to all fifty states and the District of Columbia.
2. The Federal Food, Drug and Cosmetic Act ("FDCA"), among other things governs the lawful interstate distribution of drugs for human use. As codified at Title 21, United States Code, Sections 331 *et seq.*, and specifically at § 355(b), the FDCA, and its implementing regulations, require that before a new drug may legally be distributed in interstate commerce, a sponsor of a new drug product must submit a New Drug Application ("NDA").
3. The FDCA required, at 21 U.S.C. § 355, that the NDA sponsor submit to the United States Food and Drug Administration ("FDA"), as part of an NDA, proposed labeling for the proposed intended uses for the drug which included, among other things, the conditions for therapeutic use. The NDA must also provide, to the satisfaction of FDA, data generated in

randomized and well-controlled clinical trials that demonstrates that the drug will be safe and effective when used in accordance with the proposed labeling.

4. The FDCA, at 21 U.S.C. § 355, prohibited the introduction into interstate commerce of any new drug, unless an approval of an NDA is effective. Only after the NDA, including the proposed labeling, was reviewed and approved by FDA, was the sponsor permitted by law to promote and market the drug, and only for the medical conditions of use specified in the approved labeling, for which use FDA had found sufficient evidence of safety and effectiveness. Uses unapproved by FDA, not included in the drug's approved labeling, are known as "unapproved uses" or "off-label uses."

5. The FDCA, and the regulations promulgated thereunder, required that in order to label or promote a drug for a use different than the conditions for use specified in the approved labeling, the sponsor had to file a new NDA, or amend the existing NDA, by, among other requirements, submitting the newly proposed indications for use and evidence, in the form of randomized and well-controlled clinical studies, sufficient to demonstrate that the drug would be safe and effective for the newly proposed therapeutic use or uses. Only upon approval of the new NDA could the sponsor promote the drug for the new intended use.

6. The FDCA, at 21 U.S.C. § 352(f)(1), provided that a drug was misbranded if, among other things, the labeling did not contain adequate directions for use. As the phrase is used in the FDCA, adequate directions for use cannot be written for medical indications or uses for which the drug had not been proven to be safe and effective through well-controlled clinical studies because that would be misleading under Section 352(a).

7. The FDCA, 21, U.S.C. §§ 331(a)(d), 333(a), and 355, prohibits the distribution in interstate commerce of an unapproved new drug or of a misbranded drug.

8. In or about 1993, WARNER-LAMBERT submitted an NDA for approval of a drug called Neurontin (also known by the chemical name gabapentin), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3 (h)(4) and (5). In that application, WARNER-LAMBERT sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. On or about December 30, 1993, FDA approved Neurontin for that specific use only. This approved use for Neurontin will be referred to throughout this Information as the "Approved Use." Because WARNER-LAMBERT had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than the Approved Use. Further, Neurontin was not, pursuant to 21 U.S.C. § 355(i), exempt from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

9. As described in this Information, from at least June of 1995 through at least August 20, 1996, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD); and migraine headaches, among other uses.

These and other unapproved uses for Neurontin will be collectively referred to in this Information as the "Unapproved Uses."

10. WARNER-LAMBERT did not file a new NDA seeking FDA approval for any of these Unapproved Uses during the time period addressed in this Information. Of these Unapproved Uses, only post-herpetic neuralgia has ever received FDA approval, and that approval was applied for and received after the events described in this Information.

WARNER-LAMBERT'S STRATEGY FOR NEURONTIN

11. WARNER-LAMBERT conducted evaluations of the market potential for certain of the Unapproved Uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

12. In or about the fall of 1995, WARNER-LAMBERT's Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including conference calls on pain and a pain consultant meeting.

13. Certain of WARNER-LAMBERT's annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies, and tactics for increasing sales of the Unapproved Uses of the drug. The marketing plans budgeted for and funded these tactics.

14. From early 1995, on repeated occasions, WARNER-LAMBERT determined not to seek FDA approval for certain Unapproved Uses.

15. In or about April and May of 1995, WARNER-LAMBERT performed a Marketing Assessment of proposed psychiatric indications for Neurontin. In that Marketing Assessment, WARNER-LAMBERT forecast potential revenue from Neurontin for bipolar and anxiety treatment under two scenarios: with and without FDA approval. WARNER-LAMBERT's Neurontin Development Team and New Product Committee reviewed the potential psychiatric uses and concluded that the company would not seek approval to promote and sell the drug for these Unapproved Uses.

16. In or about July of 1995 WARNER-LAMBERT's assessment of Neurontin's market potential for neuropathic pain was distributed to its Neurontin Development Team and to a WARNER-LAMBERT Vice President for Marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to FDA for approval.

17. One of the principal factors WARNER-LAMBERT considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that WARNER-LAMBERT had been developing. The company expected this new drug would be approved by FDA not only for epilepsy but also for a variety of uses beyond Neurontin's Approved Use.

18. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in WARNER-LAMBERT's original NDA approval for Neurontin. If WARNER-LAMBERT sought and obtained approval for any of the

Unapproved Uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those Unapproved Uses. WARNER-LAMBERT was concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

WARNER-LAMBERT'S PROMOTION OF NEURONTIN FOR UNAPPROVED USES

19. From in or about June of 1995 through in or about August 20, 1996, by certain of the conduct described in greater detail below, WARNER-LAMBERT promoted the sale and use of Neurontin for certain conditions other than the Approved Use in Massachusetts and elsewhere:

OFF-LABEL PROMOTION THROUGH SALES REPRESENTATIVES

20. In October 1995, a member of WARNER-LAMBERT's Epilepsy Disease Team circulated a memorandum to a group including other senior members of WARNER-LAMBERT's Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 WARNER-LAMBERT sales representatives for whom data was available in a two month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

21. On or about July 10, 1996, a WARNER-LAMBERT sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

22. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales

representatives could do lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

OFF-LABEL PROMOTION THROUGH MEDICAL LIAISONS

23. WARNER-LAMBERT employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following occasion, a WARNER-LAMBERT medical liaison promoted Neurontin for Unapproved Uses:

(a) In or about June of 1996, a WARNER-LAMBERT sales representative requested that a WARNER-LAMBERT medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for Unapproved Uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of Unapproved Uses.

(e) After the presentation, a WARNER-LAMBERT Medical Director praised the event as "another great example of use of the medical liaisons" and an Area Business Manager called it an "outstanding utilization of . . . one of the medical affairs liaisons."

24. In or about May 1996, a WARNER-LAMBERT Medical Director based in the Northeast CBU sent a voicemail message to the Medical Liaisons in the Northeast CBU in which he stated:

What we'd like you to do is, any time you're called out just make sure that your main focus out of what you're doing is on Neurontin . . . When we get out there, we want to kick some ass, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do.

One or more Medical Liaisons in the Northeast CBU interpreted this statement to mean that he or she should promote Neurontin for Unapproved Uses and thereafter, in or about May and June 1996, promoted Neurontin for neuropathic pain, an unapproved use.

OFF-LABEL PROMOTION THROUGH CONSULTANTS' MEETINGS  
AND ADVISORY BOARDS

25. WARNER-LAMBERT organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to Unapproved Uses of Neurontin.

26. WARNER-LAMBERT invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, WARNER-LAMBERT paid for accommodations and meals for the invited doctors and

their spouse or guest, and paid an honorarium to each of the doctor attendees. Doctors who acted as faculty were paid between \$1,500 and \$2,000.

27. Among the presentations made to the physicians in attendance was one relating to Unapproved Uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

28. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol, and pain.

29. On or about May 8, 1996, following the Jupiter Beach conference, WARNER-LAMBERT circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations. WARNER-LAMBERT told its employees that: "[t]he meeting was a great success and the participants were delivered a hard-hitting message about Neurontin." WARNER-LAMBERT distributed to these employees a form entitled "Jupiter Beach Trending Worksheet" which was intended to be used to gauge the effect of the meeting on the prescribing by doctors who attended the Jupiter Beach meeting.

30. From August 1-5, 1996, WARNER-LAMBERT organized an "advisory board meeting," in Atlanta, Georgia in conjunction with the 1996 Summer Olympics. WARNER-LAMBERT expressly instructed several of the physician speakers to address some of the Unapproved Uses.

31. During that meeting, WARNER-LAMBERT hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. The company had already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on WARNER-LAMBERT's behalf at prior meetings.

32. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

OFF-LABEL PROMOTION THROUGH TELECONFERENCES

33. In or about January, 1996, a WARNER-LAMBERT Vice President of the Southeast Customer Business Unit sent a memorandum to WARNER-LAMBERT sales representatives listing certain goals, including: "Utilize the Medical Liaison Group to target the Neurontin, Pain & Psychiatric market. Objective to conduct twice weekly Pain Teleconferences moderated by key Neuro Consultants. Goals 250 Physicians Participants quarterly."

34. On or about March 1, 1996, WARNER-LAMBERT sponsored such a teleconference moderated by a WARNER-LAMBERT employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

35. On or about March 28, 1996, a WARNER-LAMBERT Medical Director in the Northcentral Customer Business Unit sent a memorandum to WARNER-LAMBERT Medical Liaisons in that unit instructing them to hold a series of teleconferences with doctors to provide clinical updates on Neurontin, including monotherapy epilepsy data and non-epilepsy use data entitled "Neurontin, A Clinical Update."

36. In or about May, 1996, a WARNER-LAMBERT Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

**COUNT ONE: 21 U.S.C. §§ 331(d), 333(a)(2) & 355(a)**

**(Distribution of an Unapproved New Drug)**

37. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

38. Beginning as early as in or about April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts, and elsewhere,

**WARNER-LAMBERT,**

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses. No approval, pursuant to 21 U.S.C. § 355, was in effect with respect to Neurontin for use in these conditions.

All in violation of 21 U.S.C. §§ 331(d), 333(a)(2), and 355(a).

**COUNT TWO: 21 U.S.C. §§ 331(a), 333(a)(2) & 352(f)(1)**

**(Distribution of a Misbranded Drug: Inadequate Directions for Use)**


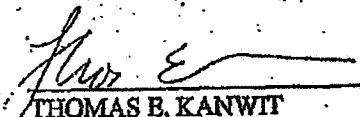
39. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

40. Beginning as early as April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts and elsewhere,

**WARNER-LAMBERT,**

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses, and which was misbranded within the meaning of 21 U.S.C. § 352(a), in that Neurontin's labeling lacked adequate directions for such uses.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(f)(1).

  
MICHAEL J. SULLIVAN  
UNITED STATES ATTORNEY  
DISTRICT OF MASSACHUSETTS  
THOMAS B. KANWIT  
ASSISTANT U.S. ATTORNEY

May 13, 2004

EFiled: Jul 7 2006 2:01PM  
Transaction ID 11728078



**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE  
IN AND FOR NEW CASTLE COUNTY**

KELLY A. TILLEY, as Personal  
Representative of the Estate of  
DANA ANDREW TILLEY, Deceased,

Plaintiff,

vs.

PFIZER INC., PARKE-DAVIS,  
a division of Warner-Lambert Company  
and Warner-Lambert Company LLC,  
WARNER-LAMBERT COMPANY and  
WARNER-LAMBERT COMPANY LLC,

Defendants.

Civil Action No. 06C-07-046 RRC

**NON-ARBITRATION CASE**

**JURY OF TWELVE DEMANDED**

**PLAINTIFF'S STATEMENT IN  
ACCORDANCE WITH FORM 3A and FORM 30**

1. Give the name and present address or last known residential and employment address and telephone no. of each eyewitness to the incident which is the subject of the litigation.

ANSWER: See death certificate and police report attached.

2. Give the name and present or last known residential and employment address and telephone number of each person who has knowledge of the facts relating to the litigation.

ANSWER: Plaintiff's decedent was treated by:

James Newman, Rheumatology Associates, 1815 West 13<sup>th</sup> Street  
Wilmington, DE 19808

Craig Sternberg, 2600 Glasgow Avenue, Glasgow, DE 19702

Frank Falco, 126 East High Street, Elkton, MD 21921

Scott Houser, P.O. Box 8286, Wilmington, DE 19803

Shala Mousai, 701 Middleford Rd., Seaford, DE 19973

3. Give the names of all persons who have been interviewed in connection with the above litigation, including the names and present or last known residential and employment addresses and telephone numbers of the persons who made said interviews and the names and present or last known residential and employment addresses and telephone numbers of persons who have the original and copies of the interview.

ANSWER: Not applicable.

4. Identify all photocopies, diagrams, or other representations made in connection with the matter in litigation, giving the name and present or last known residential and employment address and telephone number of the person having the original and copies thereof. (In lieu thereof, a copy can be attached.)

ANSWER: See attached death certificate and police report.

5. Give the name, professional address, and telephone number of all expert witnesses presently retained by the party together with the dates of any written opinions prepared by said expert. If an expert is not presently retained, described, by type, the experts whom the party expects to retain in connection with the litigation.

ANSWER: No experts retained at this time.

6. Give a brief description of any insurance, including excess coverage, that is or may be applicable to the litigation, including:

- a. The name and address of all companies insuring the risk;
- b. The policy numbers;
- c. The type of insurance;
- d. The amounts of primary, secondary, and excess coverage;

ANSWER: Not applicable.

7. Give the name, professional address and telephone number of all physicians, chiropractors, psychologists and physical therapists who have examined or treated you at any time during the ten year period immediately prior to the date of the incident in this litigation.

ANSWER: See #2 above.

8. Photocopies of existing documentary evidence relating to special damages (or, in lieu thereof, a brief sworn statement as to any item not included as to the reason of its non-availability and a specific undertaking as to when it will be made available).

ANSWER: Not applicable.

9. In any case in which lost wages or salary is claimed, photocopies of pertinent portions of the income tax returns of the Plaintiff or Plaintiffs for the past three years either as an exhibit to the Complaint or contained in a sealed envelope, or a sworn statement that the copies of the returns are in the Plaintiff's possession or have been applied for and a specific undertaking to supply them forthwith and without further request when an appearance is made on behalf of the Defendant. If a counterclaim, crossclaim, or Third-Party Complaint for personal injuries is filed, the claimant shall be required of a Plaintiff in a claim for personal injuries.

ANSWER: To be provided.

Ramunno, Ramunno & Scerba, P.A

By: /s/ L. VINCENT RAMUNNO, ESQ  
L. Vincent Ramunno (#594)  
903 N. French Street  
Wilmington, DE 19801  
(302)656-9400

## CERTIFICATION OF VITAL RECORD

CERTIFICATE OF DEATH  
State of Delaware

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

STATE FILE NO.

OFFICE OF  
VITAL  
STATISTICS

LOCAL REG. NO.

DECEDENT

TO FUNERAL DIRECTOR: After certificate has been signed by attending physician and completely filled in by funeral director, remove carbon, file parts 1 and 2 with Registrar within 72 hrs. after death and then use Burial-Transit Permit for disposition of body.

1. DECEDENT'S NAME (FIRST, MIDDLE, LAST) **DANA ANDREW TILLEY** 2. SEX **MALE** 3. DATE OF DEATH (MO., DAY, YR) **JULY 9, 2002**

4. SOCIAL SECURITY NO. **222-56-9243** 5A. AGE (YR) **35** 5B. UNDER 1 YEAR MONTHS **0** 5C. UNDER 1 DAY HOURS **0** 6. DATE OF BIRTH (MO., DAY, YR) **DEC. 27, 1966** 7. BIRTHPLACE (CITY AND STATE OR FOREIGN COUNTRY) **WILMINGTON, DE**

8. WAS DECEDENT EVER IN U.S. ARMED FORCES? ☐ YES ☒ NO 9. ANATOMICAL GIFT ☐ DONOR ☒ NOT GRANTED 10A. PLACE OF DEATH (CHECK ONLY ONE, SEE INSTRUCTIONS ON OTHER SIDE) ☐ HOSPITAL ☐ DEPARTMENT ☐ RESIDENT ☐ OTHER ☒ HOME ☐ OTHER (SPECIFY) **BEAR** 10B. CITY, TOWN, OR LOCATION OF DEATH **BEAR** 10C. COUNTY OF DEATH **N.C.**

11. MARITAL STATUS — (MARRIED, NEVER MARRIED, WIDOWED, DIVORCED (SPECIFY)) **MARRIED** 12. MOST RECENT SPOUSE (LIVING OR DECEASED) (NAME IF WIFE) **KELLY A. (FISHER)** 13A. DECEDENT'S USUAL OCCUPATION (AND OF WORK DURING MOST OF WORKING LIFE, DO NOT USE RETIRED) **DISABLED** 13B. KIND OF BUSINESS/INDUSTRY **NONE**

14A. RESIDENCE — STATE **DELAWARE** 14B. COUNTY **N.C.** 14C. CITY, TOWN, OR LOCATION **BEAR** 14D. STREET AND NUMBER **103 PIGEON RUN DRIVE**

15. RACE — AMERICAN INDIAN, BLACK, WHITE, ETC. (SPECIFY) **WHITE** 16. DECEDENT'S EDUCATION (SPECIFY ONLY HIGHEST GRADE COMPLETED) **12** 17. COLLAGE (1-4 OR 5-12) **12**

18. FATHER'S NAME (FIRST, MIDDLE, LAST) **ISAAC TILLEY** 19. MOTHER'S NAME (FIRST, MIDDLE, MAIDEN SURNAME) **NORMA (HOLLIS)**

PARENTS

INFORMANT

20A. INFORMANT'S NAME (TYPE PRINT) **KELLY A. TILLEY/WIFE** 20B. MAKING ADDRESS (STREET AND NUMBER OR RURAL ROUTE NUMBER, CITY OR TOWN, STATE, ZIP CODE) **103 PIGEON RUN DRIVE BEAR, DE 19701**

21A. METHOD OF DISPOSITION ☐ BURIAL ☒ CREMATION ☐ REMOVAL FROM STATE ☐ OTHER (SPECIFY) **HOCKESSIN CREMATORY CO. HOCKESSIN, DE**

21B. PLACE OF DISPOSITION (NAME OF CEMETERY, CREMATORY, OR OTHER PLACE) **HOCKESSIN CREMATORY CO. HOCKESSIN, DE**

21C. LOCATION (CITY, TOWN, STATE) **HOCKESSIN, DE**

DISPOSITION

22A. SIGNATURE OF FUNERAL DIRECTOR *James P. Muller* 22B. LICENSE NUMBER (OF LICENSEE) **K10000529** 23. NAME AND ADDRESS OF FUNERAL HOME **BOHERTY FUNERAL HOMES, INC. 1900 DELAWARE AVE. WILM, DE 19806**

24. SIGNATURE OF DECEASED *Dana Andrew Tilley* 25. DATE OF DEATH (MO., DAY, YR) **JUL 12 2002**

26. SIGNATURE OF DECEASED *Dana Andrew Tilley* 27. LICENSE NUMBER **C10005019** 28. DATE SIGNED (MO., DAY, YR) **7/9/02**

PRONOUNCING PHYSICIAN

ITEMS 27-29 MUST BE COMPLETED BY PHYSICIAN OR NURSE WHO PRONOUNCES DEATH

27. TIME OF DEATH **0603** 28. DATE PRONOUNCED DEAD (MO., DAY, YR) **7/9/02** 29. WAS CASE REFERRED TO MEDICAL EXAMINER (YES OR NO) **YES**

SEE DEFINITION ON OTHER SIDE

CERTIFIED

30A. CERTIFIER (CHECK ONLY ONE) ☐ CERTIFYING PHYSICIAN (Physician certifying cause of death when another physician has pronounced death and completed item 29) To the best of my knowledge, death occurred due to the cause(s) and manner as stated.

30B. CERTIFYING AND PRONOUNCING PHYSICIAN (Physician both pronouncing death and certifying the cause of death) To the best of my knowledge, death occurred at the time, date, and place, and due to the cause(s) and manner as stated.

30C. MEDICAL EXAMINER (On the basis of examination and/or investigation, in my opinion, death occurred at the time, date, and place, and due to the cause(s) and manner as stated.)

30D. SIGNATURE AND TITLE OF CERTIFIER *Adrienne Sekula-Perlman, M.D.* **DEPUTY CHIEF MEDICAL EXAMINER** 30E. LICENSE NUMBER **C10004375** 30F. DATE SIGNED (MO., DAY, YR) **JULY 10, 2002**

31. NAME AND ADDRESS OF CERTIFIER WHO COMPLETED CAUSE OF DEATH (ITEM 40) (TYPE PRINT) **ADRIENNE SEKULA-PERLMAN, M.D., 200 SOUTH ADAMS STREET, WILMINGTON, DE 19801**

32A. WAS AN AUTOPSY PERFORMED? ☐ YES ☒ NO 32B. MANNER OF DEATH ☐ NATURAL ☒ ACCIDENT ☐ SUICIDE ☐ HOMICIDE ☐ PENDING INVESTIGATION ☐ UNDETERMINED

33. DATE OF INJURY (MO., DAY, YR) **7/9/02** 34. TIME OF INJURY **FOUND 5:30** 35. PLACE OF INJURY (AT HOME, FARM, STREET, FACTORY, OFFICE, MAINTENANCE, ETC. (SPECIFY)) **IN THE GARAGE OF RESIDENCE**

36. LOCATION (STREET AND NUMBER OR RURAL ROUTE NUMBER, CITY OR TOWN, STATE) **103 PIGEON RUN DRIVE, BEAR, DE**

37. DESCRIBE HOW INJURY OCCURRED **HANGED SELF.**

38. PART I DO NOT ENTER THE MODE OF DYING SUCH AS CARDIAC OR RESPIRATORY ARREST, SHOCK, OR HEART FAILURE. LIST ONLY ONE CAUSE PER EACH LINE. (APPROPRIATE INTERVAL BETWEEN ONSET AND DEATH)

IMMEDIATE CAUSE (A) **HANGING**

CAUSE DUE TO (B)

CAUSE DUE TO (C)

CAUSE DUE TO (D)

PART II OTHER SIGNIFICANT CONDITIONS — CONTRIBUTING TO CAUSE OF DEATH

39. PART II OTHER SIGNIFICANT CONDITIONS — CONTRIBUTING TO CAUSE OF DEATH

TO HOSPITAL OR PHYSICIAN — DELAWARE LAW REQUIRES THAT THE DEATH CERTIFICATE BE EXECUTED WITHIN 72 HOURS AFTER DEATH.

(1) ORIGINAL COPY—STATE

This is to certify that this is a true and correct reproduction or abstract of the official record filed with the Delaware Division of Public Health.

Any alteration of this document is prohibited. Do not accept unless on security paper with the raised seal of the Office of Vital Statistics.

State Registrar

Page: 1 Report Date: 07/09/2002 Agency: New Castle County PD  
 Reported Date and Time: TUE 07/09/2002 0542 Initial Crime Report  
 Location: 103 Pigeon Run DR Pigeon Run BEAR, DE 19701  
 EFiled: JUL 7 2006 2:01 PM  
 Transaction ID 11728078  
 TUE 07/09/2002 0001 thru TUE 07/09/2002 0001



M.O. and Incident Overview:  
 WRITER RESPONDED TO THE ABOVE LOCATION IN REFERENCE TO A DEATH INVESTIGATION.

Grid: 082-328 Sector: 33 County: New Castle Domestic Related: Yes ☒ No ☐ 4-F-14 Sent: Yes ☒ No ☐ Gen Broadcast Sent: Yes ☐ No ☒

## Victim Information

Victim Number: 001 Name: TILLEY, DANA ANDREW  
 Type: Individual Sex: Male Race: White Ethnic Origin: Non-Hispanic Age: 35 D.O.B.: 12/27/1966  
 Address: 103 Pigeon Run DR Pigeon Run BEAR, DE 19701 Resident Status: Full Time Home Telephone: (302) 832-0878 Employer/School: DISABLED Work Telephone:  
 Reporting Person? Yes ☒ No ☐ Victim Injured? Yes ☒ No ☐ Victim Deceased? Yes ☒ No ☐ Officer Comments:  
 Injuries: Description of Injuries:

## Crimes and Associated Information

Victim Number: 001 Crime Seq: 001 Statute: Crime Description: Death Investigation--No Specific Charges Associated  
 Location Of Offense: Residence/Home/Garage Status: Pending-Active Involvement: Alcohol ☐ Drugs ☐ Computer ☐ General Offense:  
 Suspected Hate/Bias: Yes ☒ No ☐ N/A Crime Code: 8104 - Sudden Death/Death Investigation  
 Burglary Force Involved: Yes ☐ No ☒

## Witness Information

Sequence: 001 Type: Reporting Person Name: TILLEY, KELLY A Sex: Female Race: White Age: 35 D.O.B.: 01/17/1967  
 Address: 103 Pigeon Run DR Pigeon Run BEAR, DE 19701 Home Telephone: (302) 832-0878 Employer/School: Work Telephone:  
 Sequence: 002 Type: Living With Name: TILLEY, CHASITY L Sex: Female Race: White Age: 16 D.O.B.: 11/13/1985  
 Address: 103 Pigeon Run DR Pigeon Run BEAR, DE 19701 Home Telephone: Employer/School: Work Telephone:  
 Parent/Guardian Information: KELLY TILLEY Same Address as Witness Parent Telephone:  
 Sequence: 003 Type: Living With Name: TILLEY, JOSHUA I Sex: Male Race: White Age: 15 D.O.B.: 07/06/1987  
 Address: 103 Pigeon Run DR Pigeon Run BEAR, DE 19701 Home Telephone: Employer/School: Work Telephone:  
 Parent/Guardian Information: KELLY A TILLEY Same Address as Witness Parent Telephone:  
 Sequence: 004 Type: Living With Name: TILLEY, ROBERT A Sex: Male Race: White Age: 10 D.O.B.: 04/20/1992  
 Address: 103 Pigeon Run DR Pigeon Run BEAR, DE 19701 Home Telephone: Employer/School: Work Telephone:  
 Parent/Guardian Information: KELLY TILLEY Same Address as Witness Parent Telephone:  
 Sequence: 005 Type: Parent Name: TILLEY, KELLY Sex: Unknown Race: White Age: D.O.B.:  
 Address: 103 Pigeon Run DR Pigeon Run BEAR, DE 19701 Home Telephone: Employer/School: Work Telephone:  
 Sequence: 006 Type: Parent Name: TILLEY, KELLY A Sex: Unknown Race: White Age: D.O.B.:

Reporting Officer:  
 OFC ARGOE - 2503 2

Supervisor Approval:  
 DANIEL C YEAGER OJNCDCY Date 07/09/2002 1548

Page: 2 Report Date: 07/09/2002 Agency: New Castle County PD Complaint: 32-02-066420

Sequence  
006 Continued

### Witness Information

Address 103 Pigeon Run DR Pigeon Run BEAR, DE 19701		Home Telephone	Employer/School	Work Telephone
Sequence 007	Type Parent	Name TILLEY, KELLY	Sex Unknown	Race
Address 103 Pigeon Run DR Pigeon Run BEAR, DE 19701		Home Telephone	Employer/School	Work Telephone
		Age	D.O.B.	

### Investigative Narrative

ON THE ABOVE DATE AND TIME, WRITER RESPONDED TO 103 PIGEON RUN DR. PIGEON RUN WHICH IS A TWO STORY SINGLE DWELLING RESIDENCE IN REFERENCE TO A DEATH INVESTIGATION. UPON ARRIVAL, WRITER SPOKE WITH OFFICER WEGLARZ IN REFERENCE TO INVESTIGATION. WRITER WAS ADVISED BY OFFICER WEGLARZ THAT V-1 HAD BEEN SUFFERING FROM FIBROMYALGIA FOR THE PAST FIVE TO SIX YEARS. WRITER LEARNED THAT V-1 HAD AN INDUSTRIAL ACCIDENT IN 1994/1995 AND WAS LEFT WITH MEDICAL CONDITION. WRITER WAS ADVISED THAT V-1'S CONDITION LEFT HIM DEPRESSED AND UNABLE TO FUNCTION AT TIMES. WRITER WAS ADVISED THAT V-1'S WIFE, KELLY TILLEY, WOKE THIS AM AND NOTICED HER HUSBAND WAS NOT IN BED. WRITER WAS ADVISED THAT HE HAD GOT OUT OF BED AROUND MIDNIGHT. WRITER LEARNED THAT V-1'S WIFE, RP, CHECKED THE RESIDENCE AND FOUND V-1 HANGING FROM A ROPE IN THE GARAGE. WRITER LEARNED THAT THE RP WENT TO THE KITCHEN TO GET A KNIFE AND CUT V-1 DOWN (NOTE: KNIFE AND CUT ROPE WAS LEFT INSIDE CRIME SCENE). WRITER WAS ADVISED BY OFFICER WEGLARZ THAT V-1 HAD BEEN PRONOUNCED AT 0603 HRS BY DR.

LEVINE #34 AT CHRISTIANA HOSPITAL. WRITER LEARNED THAT V-1 WAS CURRENTLY TAKING THE FOLLOWING MEDICATION: WELLBUTRIN 100MG, DIAZEPAM 10 MG, MORPHINE SUL 15 MG, MORPHINE SUL 60 MG, NEURONTIN 600MG AND AMPHER SALT C 30 MG.

WRITER STOOD BY SCENE UNTIL RELIEVED BY OFFICER SARNECKY AT 0740HRS.

Reporting Officer  
OFC ARGOE - 2503 2  
Detective Notified

Supervisor Approval  
DANIEL C YEAGER OJNCDCY Date 07/09/2002 1548

Referred To

Solvability Factors

Witness  
Suspect Located

J.M.O.  
Suspect Described

Trace Stolen Property  
Suspect Identified

Suspect Named  
Suspect Vehicle Identified

Status  
Has Follow Up

Page: 1 Report Date: 07/09/2002 Agency: New Castle County PD Complaint: 32-02-066420

## Supplemental Report

Original Occurrence Dates and Times:

TUE 07/09/2002 0001 thru TUE 07/09/2002 0540

Grid

082-328

Sector

33

Original Location:

103 Pigeon Run DR Pigeon Run BEAR, DE 19701

## Investigative Narrative

On 070902 at approximately 0610 hours I responded to 103 Pigeon Run Dr.

reference a possible suicide. On arrival I noted that Sgt. Merrill and Off.

Weglarz were already on scene. I was relieved by Officers Argoe and Sarnecky reference responding to court.

Prior to clearing the scene I conducted a brief neighborhood canvass (results below).

No further action by writer.

## Canvass:

2 Gaynor Court, Pigeon Run, Bear, DE 19701. Negative results (advised by passerby that the residence is vacant).

1 Gaynor Court, Pigeon Run, Bear, DE 19701. Tennant, Marjorie WFN 112127 302-834-7763. Subject advised that she was unfamiliar with the victim or his family.

2 Vellan Dr., Pigeon Run, Bear, DE 19701. DuHadaway, David WMN 040447 302-834-1668. Subject stated 'I couldn't even tell you their name.'

56 Rawlings Dr., Pigeon Run, Bear, DE 19701. Howell, Jon WMN 102457 302-834-4011 (residence behind the victim's residence). Subject advised that he could only state that the family had a dog that barked a lot.

Reporting Officer

OFC DULIN - 25632 001

Solvability Factors

Witness

Suspect Located

M. O.

Suspect Described

Supervisor Approval

DANIEL C YEAGER OJNCDCY Date 07/09/2002

Trace Stolen Property

Suspect Identified

Suspect Named

Suspect Vehicle Described

Status

Page: 1 Report Date: 07/10/2002 Agency: New Castle County PD Complaint: 32-02-066420

## Supplemental Report

## Original Occurrence Dates and Times:

TUE 07/09/2002 0001 thru TUE 07/09/2002 0540

## Grid

082-328

## Sector

33

## Original Location:

103 Pigeon Run DR Pigeon Run - BEAR, DE 19701

## Investigative Narrative

ON 070902, WRITER RESPONDED TO 103 PIGEON RUN DR TO ASSIST IN A SUICIDE INVESTIGATION. UPON ARRIVAL, WRITER RELIEVED OFC ARGOE AT 0740 AND HELD THE SCENE W/ CIU UNTIL THE MEDICAL EXAMINER ARRIVED. WRITER THEN CLEARED THE SCENE WHEN AUTHORIZED BY SGT MCGOWAN.

## Reporting Officer

PFC SARNECKY - 25242 002

## Solvability Factors

## Witness

L. Suspect Located

## M. O.

Suspect Described

## Supervisor Approval

DANIEL C YEAGER OJNCDCY Date 07/10/2002

Trace Stolen Property

Suspect Identified

Suspect Named

Suspect Vehicle Described

Status

## **EXHIBIT B**

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARILYN BLACKWELL : CIVIL ACTION  
:   
v. : NO. 06-2295  
:   
PFIZER, INC., et al. :

**ORDER**

AND NOW, this        day of July, 2006, upon consideration of Defendants Pfizer Inc., Warner-Lambert Company, Warner Lambert Company LLC, and Parke-Davis's Motion for Stay Pending MDL Transfer (docket no. 9), it is **ORDERED** that Defendants' Motion is **GRANTED**, and all proceedings are **STAYED** pending a decision by the Judicial Panel on Multidistrict Litigation ("Panel").

BY THE COURT:

/s/ Bruce W. Kauffman  
BRUCE W. KAUFFMAN, J.

## **EXHIBIT C**

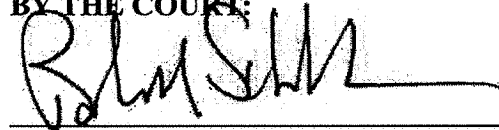
**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>BRENT D. YOUNG &amp; JODIE YOUNG,</b>	:	
<b>Plaintiffs,</b>	:	<b>CIVIL ACTION</b>
	:	
<b>v.</b>	:	
	:	
<b>PFIZER INC.,</b>	:	
<b>WARNER-LAMBERT COMPANY,</b>	:	
<b>WARNER-LAMBERT LLC, on its own</b>	:	
<b>behalf and on behalf of its</b>	:	
<b>unincorporated division, Parke-Davis,</b>	:	<b>No. 06-1308</b>
<b>Defendants.</b>	:	

**ORDER**

**AND NOW**, this 3<sup>rd</sup> day of **May, 2006**, upon consideration of Defendants' Motion to Stay Proceedings Pending MDL Transfer and Plaintiffs' response thereto, it is hereby **ORDERED** that Defendants' motion (Document No. 7) is **GRANTED**.

**BY THE COURT:**



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**Berle M. Schiller, J.**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

KELLY A. TILLEY, as Personal  
Representative of the Estate of  
DANA ANDREW TILLEY, Deceased,

Plaintiff,

vs.

PFIZER INC., PARKE-DAVIS, a division  
of Warner-Lambert Company and  
Warner-Lambert Company LLC,  
WARNER-LAMBERT COMPANY and  
WARNER-LAMBERT COMPANY LLC,

Defendants.

Civil Action No. \_\_\_\_\_

**CERTIFICATE OF SERVICE**

I, David E. Wilks, hereby certify that on the 17<sup>th</sup> day of August, 2006, I caused a true and correct copy of a *Notice to Adverse Party of Filing of Notice of Removal* and a *Notice of Removal* to be served on the counsel for the plaintiff listed below, via U.S. Mail:

Andrew Finkelstein, Esq.  
FINKELSTEIN & PARTNERS, LLP  
436 Robinson Avenue  
Newburgh, New York 12550

L. Vincent Ramunno, Esq.  
RAMMUNO, RAMMUNO & SCERBA, P.A.  
903 French Street  
Wilmington, DE 19801

Dated: August 17, 2006



David E. Wilks (DE ID 2793)

**COVER SHEET**

The US civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of the Court for purposes of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

<b>I. (a) PLAINTIFF: KELLEY A. TILLEY/DANA ANDREW TILLEY (Dec'd)</b> (b) County of Residence of First Listed Plaintiff: NEW CASTLE COUNTY  (EXCEPT IN US PLAINTIFF CASES)		<b>DEFENDANTS: PFIZER INC. PARKE-DAVIS, WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC</b> County of Residence of First Listed Defendant (IN US PLAINTIFF CASES ONLY) Note: In land condemnation cases, use the location of the tract of land involved.	
(c) Attorneys (Firm Name, Address, and Telephone Number) I. Vincent Ramunno, RAMMUNO, RAMMUNO & SCERBA, P.A., 903 French Street, Wilmington, DE 19801		Attorneys (If Known) David E. Wilks (DE No. 2793) REED SMITH LLP, 1201 Market Street, Suite 1500 Wilmington, DE 19801	

<b>II. BASIS OF JURISDICTION</b> (Place an x in one box only)	<b>III. CITIZENSHIP OF PRINCIPAL PARTIES</b> (Place an x in one box for Plaintiff and one box for Defendant) (For Diversity Cases Only)																
<input type="checkbox"/> 1. US Government Plaintiff <input type="checkbox"/> 2. US Government Plaintiff <input checked="" type="checkbox"/> 3. Federal Question US Government Not Party Plaintiff <input type="checkbox"/> 4. Diversity (Indicate Citizenship of Parties in Item (III))	<table style="width:100%; border-collapse: collapse;"> <tr> <th style="text-align: left; border-bottom: 1px solid black;">PTF</th> <th style="text-align: left; border-bottom: 1px solid black;">DEF</th> <th style="text-align: left; border-bottom: 1px solid black;">PTF</th> <th style="text-align: left; border-bottom: 1px solid black;">DEF</th> </tr> <tr> <td>Citizen of This State</td> <td><input type="checkbox"/></td> <td>Incorporated or Principal Place of Business in This State</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Citizen of Another State</td> <td><input type="checkbox"/></td> <td>Incorporated and Principal Place of Business in Another State</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td><input type="checkbox"/></td> <td>Incorporated and Principal Place of Business in Another State Foreign Nation</td> <td><input type="checkbox"/></td> </tr> </table>	PTF	DEF	PTF	DEF	Citizen of This State	<input type="checkbox"/>	Incorporated or Principal Place of Business in This State	<input type="checkbox"/>	Citizen of Another State	<input type="checkbox"/>	Incorporated and Principal Place of Business in Another State	<input type="checkbox"/>	Citizen or Subject of a Foreign Country	<input type="checkbox"/>	Incorporated and Principal Place of Business in Another State Foreign Nation	<input type="checkbox"/>
PTF	DEF	PTF	DEF														
Citizen of This State	<input type="checkbox"/>	Incorporated or Principal Place of Business in This State	<input type="checkbox"/>														
Citizen of Another State	<input type="checkbox"/>	Incorporated and Principal Place of Business in Another State	<input type="checkbox"/>														
Citizen or Subject of a Foreign Country	<input type="checkbox"/>	Incorporated and Principal Place of Business in Another State Foreign Nation	<input type="checkbox"/>														

IV. NATURE OF SUIT (PLACE AN x IN ONE BOX ONLY)					
<b>CONTRACT</b> <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability  <b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Tort Product Liability <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>TORTS</b> <b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> Other Personal Injury  <b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 440 Other Civil Rights	<input type="checkbox"/> 362 Personal Injury - Med Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability  <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability  <b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> Other	<b>FORFEITURE/PENALTY</b> <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other  <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<b>BANKRUPTCY</b> <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157  <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark  <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395f) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))  <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (US plaintiff or Defendant) <input type="checkbox"/> 871 IRS - Third Party 28 USC 7609	<b>OTHER STATUTES</b> <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/  Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 891 Agriculture Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes <input checked="" type="checkbox"/> Other Statutory Actions

V. ORIGIN (PLACE AN x IN ONE BOX ONLY)			
<input type="checkbox"/> 1 Original Processing <input type="checkbox"/> 5 Transferred from Another District (specify)	<input type="checkbox"/> 2 Removed from State Court <input type="checkbox"/> 6 Multidistrict Litigation	<input type="checkbox"/> 3 Remanded from Appellate Court <input type="checkbox"/> 7 Appeal to District Judge from Magistrate Judgment	<input type="checkbox"/> 4 Reinstated or Reopened

**VI. CAUSE OF ACTION** (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY.) **REMOVAL OF ACTION RELTATED TO AND ARISING OUT OF 21 U.S.C. §301, et seq.**

**VII. REQUESTED IN COMPLAINT:** Check if this is a CLASS ACTION \_\_\_\_\_ DEMAND \$ \_\_\_\_\_ Check YES only if demanded in complaint:  
 JURY DEMAND: ☐ Yes ☐ No

**VIII. RELATED CASE(S) IF ANY** (See instructions): Judge \_\_\_\_\_ Docket Number \_\_\_\_\_

Date: 8/17/06 Signature of Attorney of Record: [Signature]

United States District Court

AO FORM 85 RECEIPT (REV. 9/04)

United States District Court for the District of Delaware

Civil Action No. 06-16

**ACKNOWLEDGMENT**  
**OF RECEIPT FOR AO FORM 85**

**NOTICE OF AVAILABILITY OF A**  
**UNITED STATES MAGISTRATE JUDGE**  
**TO EXERCISE JURISDICTION**

I HEREBY ACKNOWLEDGE RECEIPT OF \_\_\_\_\_ COPIES OF AO FORM 85.

8/17/06

(Date forms issued)

Patrick Boyer

(Signature of Party or their Representative)

Patrick Boyer

(Printed name of Party or their Representative)

Note: Completed receipt will be filed in the Civil Action